WEBVTT

1
00:00:20.720 --> 00:00:31.280
Nana Adjeiwaa-Manu: Good morning, everyone, and welcome to this public meeting on the reauthorization of the over-the-counter monograph drug user fee program or OMUFA.

2
00:00:31.980 --> 00:00:42.939
Nana Adjeiwaa-Manu: My name is Nana Adjeiwaa-Manu. And I am with the program evaluation and implementation staff in the center for drug evaluation and research. Or CDER.

3
00:00:43.080 --> 00:00:45.250
Nana Adjeiwaa-Manu: I will be your moderator for today.

4
00:00:45.800 --> 00:00:53.229
Nana Adjeiwaa-Manu: OMUFA authorizes FDA to collect user fees to support over-the-counter monograph drug activities.

5
00:00:53.750 --> 00:00:59.940
Nana Adjeiwaa-Manu: The current legislative authority for OMUFA expires on September 30th, 2025.

6
00:01:00.190 --> 00:01:10.989
Nana Adjeiwaa-Manu: Without new legislation, FDA will no longer be able to collect user fees for future fiscal years to help fund over the counter monograph drug activities.

7
00:01:11.330 --> 00:01:22.629
Nana Adjeiwaa-Manu: The purpose of today's hybrid public meeting is to obtain the public's views on the proposed recommendations for the reauthorization of the OMUFA program; OMUFA 2

8
00:01:22.940 --> 00:01:32.849
Nana Adjeiwaa-Manu: Today's meeting is an important step in engaging with public stakeholders on the negotiated reauthorization recommendations for the OMUFA program.

9
00:01:34.100 --> 00:01:36.920
Nana Adjeiwaa-Manu: We have a full agenda for today's meeting.

10
00:01:36.960 --> 00:01:44.309
Nana Adjeiwaa-Manu: We will begin with Dr. Patricia Cavazzoni, CDER Center Director, who will provide opening remarks.

11
00:01:59.560 --> 00:02:15.039
Dr. Patricia Cavazzoni: Good morning, everyone. It's a real pleasure to be able to welcome everyone on behalf of CDER to this public meeting to discuss proposed recommendations for the reauthorization of the OMUFA program.

12
00:02:15.720 --> 00:02:28.210
Dr. Patricia Cavazzoni: The FDA is holding this public meeting to obtain input on the negotiated reauthorization recommendations for the second iteration of the OMUFA program or OMUFA II.

13
00:02:28.980 --> 00:02:36.740
Dr. Patricia Cavazzoni: Like other FDA user fee programs, OMUFA is authorized for a five-year period and must be reauthorized to continue.

14
00:02:37.400 --> 00:02:44.010
Dr. Patricia Cavazzoni: This reauthorization provides the opportunity to apply lessons learned from previous cycles to improve the program.

15
00:02:44.930 --> 00:02:50.509
Dr. Patricia Cavazzoni: 240 million Americans use over-the-counter drugs every year.

16
00:02:51.010 --> 00:02:59.040
Dr. Patricia Cavazzoni: OTC Drugs have long provided an efficient, low-cost way for Americans to manage everyday health needs.

17
00:02:59.500 --> 00:03:05.510
Dr. Patricia Cavazzoni: and they plan and they play an increasingly vital role in our health care system.

18
00:03:06.190 --> 00:03:19.139
Dr. Patricia Cavazzoni: Although manufacturers can bring non-prescription drugs to market through a new drug application. A large portion of the OTC drug marketed in the U.S. are regulated under the OTC Monograph system.

19
00:03:19.590 --> 00:03:38.220
Dr. Patricia Cavazzoni: An OTC Monograph is a rule book for each therapeutic category, establishing conditions such as active ingredients, uses, doses, routes of administrations, labeling and testing, under which an OTC drug is generally recognized as safe and effective.

20
00:03:39.320 --> 00:03:57.940
Dr. Patricia Cavazzoni: The beginning of an exciting new chapter in OTC drug history began in March 2020, right at the beginning of the COVID-19 pandemic, when the President signed into law the Coronavirus Aid Relief and the Economic Security Act or Cares Act.

21
00:03:58.310 --> 00:04:05.909
Dr. Patricia Cavazzoni: The act included important reforms that modernize the way OTC monograph drugs are regulated in the United States.

22
00:04:07.170 --> 00:04:14.580
Dr. Patricia Cavazzoni: FDA has historically been very under-resourced for activities related to OTC drugs.

23
00:04:15.420 --> 00:04:28.809
Dr. Patricia Cavazzoni: User fees serve a vital resource for the FDA to uphold its mission of safeguarding public health while also facilitating the timely introduction of innovative FDA regulated products.

24
00:04:30.550 --> 00:04:41.560
Dr. Patricia Cavazzoni: similar to other user fee user fee programs. The 1st cycle of OMUFA was primarily focused on setting up the infrastructure necessary to implement the program.

25
00:04:42.440 --> 00:05:01.110
Dr. Patricia Cavazzoni: However, unlike the other user fee programs, the entire statutory framework for OTC monograph drugs was revised concurrently with the establishment of the OMUFA user fee program creating an additional learning curve for implementation.

26
00:05:01.210 --> 00:05:12.890
Dr. Patricia Cavazzoni: In contrast for PDUFA, the statutory framework for the new drug application was in place for decades before the user fee program was put into place.

27
00:05:14.780 --> 00:05:26.300
Dr. Patricia Cavazzoni: Over the first 4 years of the program, FDA has made huge strides in setting up the infrastructure needed to implement this major change to the monograph system.

28
00:05:26.740 --> 00:05:35.300
Dr. Patricia Cavazzoni: These accomplishments are emphasized by the fact that in some ways we had to start from scratch to build the system and the new regulatory framework.

29
00:05:36.250 --> 00:05:44.940
Dr. Patricia Cavazzoni: Now that we're beginning to get much of the infrastructure in place for OMUFA, we are excited to begin realizing the true promise of the program.

30
00:05:45.250 --> 00:05:56.559
Dr. Patricia Cavazzoni: to meaningfully advance our efforts to modernize the OTC monograph, drug development and review process by improving efficiency, timelines, and predictability.

31
00:05:57.260 --> 00:06:08.020
Dr. Patricia Cavazzoni: For example, we published the 1st FDA Initiated proposed order to address a safety issue related to Acetaminophen serious skin to skin reactions.

32
00:06:08.770 --> 00:06:14.989
Dr. Patricia Cavazzoni: FDA also issued a proposed order to address efficacy of oral phenyphrine.

33
00:06:15.520 --> 00:06:33.390
Dr. Patricia Cavazzoni: We're also particularly excited that very recently FDA received the first OTC monograph order, request to add a new sunscreen ingredient to the monograph. We're actively reviewing that submission in accordance with the timeline established in OMUFA I.

34
00:06:34.520 --> 00:06:40.029
Dr. Patricia Cavazzoni: The proposed recommendations for OMUFA II. Address many of the top priorities

35
00:06:40.120 --> 00:06:45.619
Dr. Patricia Cavazzoni: identified by interested members of the public, the regulated industry, and the FDA.

36
00:06:46.670 --> 00:06:59.540
Dr. Patricia Cavazzoni: In coming to these proposed recommendations, we also want to thank our industry representatives for working with us to address these priorities in the proposed OMUFA II Commitment letter.

37
00:07:00.390 --> 00:07:11.900
Dr. Patricia Cavazzoni: The agency's collaboration with industry is a partnership that underscores the commitment to scientific integrity, regulatory standard, patient safety, and transparency.

38
00:07:12.540 --> 00:07:24.369
Dr. Patricia Cavazzoni: Through the negotiation process the FDA and industry have been working towards the common goal of advancing public health while maintaining regulatory standards and promoting innovation.

39
00:07:25.140 --> 00:07:27.969
Dr. Patricia Cavazzoni: While some of the proposed recommendations are new,

40
00:07:28.190 --> 00:07:32.999
Dr. Patricia Cavazzoni: many either build or refine elements in the existing program.

41
00:07:33.380 --> 00:07:38.979
Dr. Patricia Cavazzoni: Among the recommendations are specific proposed enhancements in the following areas.

42
00:07:39.940 --> 00:07:41.500
Dr. Patricia Cavazzoni: Review,

43
00:07:41.710 --> 00:07:44.460
Dr. Patricia Cavazzoni: test methods in OTC monograph

44
00:07:44.470 --> 00:07:49.360
Dr. Patricia Cavazzoni: meeting, management, education, information, transparency,

45
00:07:49.370 --> 00:07:54.899
Dr. Patricia Cavazzoni: monograph product, quality enhancement and financial transparency and management.

46
00:07:56.220 --> 00:08:01.399
Dr. Patricia Cavazzoni: We especially look forward to receiving input on the reauthorization recommendations.

47
00:08:02.170 --> 00:08:08.459
Dr. Patricia Cavazzoni: Thanks to all those who are speaking and attending today, as well as those who submit comments to the public docket.

48
00:08:09.350 --> 00:08:20.370
Dr. Patricia Cavazzoni: We look forward to continuing to work with industry and other interested parties, to ensure a smooth transition to the next phase of this critical program,

49
00:08:20.380 --> 00:08:26.719
Dr. Patricia Cavazzoni: and to avoid disruption that would ultimately and certainly impact public health

50
00:08:26.870 --> 00:08:30.380
Dr. Patricia Cavazzoni: through impact of FDA. Thank you very much.

51
00:08:39.100 --> 00:08:42.179
Nana Adjeiwaa-Manu: Thank you very much Dr. Cavazzoni.

52
00:08:42.419 --> 00:08:43.420
Nana Adjeiwaa-Manu: Before I introduce the

WEBVTT

53
00:00:00.000 --> 00:00:05.500
Nana Adjeiwaa-Manu: next speaker, I'm going to go through the rest of the agenda and just provide a few housekeeping notes.

2
00:00:07.690 --> 00:00:20.679
Nana Adjeiwaa-Manu: So our next speaker will be Teresa Michele, Director of the office of Non-Prescription Drugs in CDER, and she will follow with a presentation that will provide background on OMUFA as well as the reauthorization process.

3
00:00:21.070 --> 00:00:31.459
Nana Adjeiwaa-Manu: Afterwards we will receive an overview of the OMUFA, II agreement from Karen Murray, who is the Deputy Director of the Office of Non-prescription Drugs in CDER.

4
00:00:31.770 --> 00:00:37.730
Nana Adjeiwaa-Manu: Next we will hear from Paul Phillips, who is the Director of the Office of Program Operations in CDER,

5
00:00:37.840 --> 00:00:47.579
Nana Adjeiwaa-Manu: and we will also hear from Angela Granum, who is the Division Director of the Office of Management's Division of User Fee Management or “DUFM” in CDER.

6
00:00:47.960 --> 00:00:52.659
Nana Adjeiwaa-Manu: We will then have panels that will provide perspectives from the following types of groups:

7
00:00:52.860 --> 00:00:56.930
Nana Adjeiwaa-Manu: Regulated industry and academic and advocacy groups.

8
00:00:57.390 --> 00:01:05.799
Nana Adjeiwaa-Manu: We will leave time for public comments. And Teresa Michele, Director of the Office of Non-prescription Drugs will give brief closing comments.

9
00:01:06.040 --> 00:01:09.449
Nana Adjeiwaa-Manu: I will then close the meeting around 12:30 Pm.

10
00:01:10.070 --> 00:01:14.400
Nana Adjeiwaa-Manu: The stakeholder panels will include a series of speaker presentations.

11
00:01:14.670 --> 00:01:19.059
Nana Adjeiwaa-Manu: Each speaker will have 10 minutes to present their perspective on OMUFA.

12
00:01:19.250 --> 00:01:23.569
Nana Adjeiwaa-Manu: As we do have a full agenda, we will need to adhere to that timeframe.

13
00:01:23.600 --> 00:01:27.869
Nana Adjeiwaa-Manu: It will be my job to let speakers know as they approach their time limit

14
00:01:28.410 --> 00:01:36.499
Nana Adjeiwaa-Manu: In the Federal Register notice that announced this meeting, FDA provided the following information to help panelists with framing their comments:

15
00:01:36.750 --> 00:01:40.990
Nana Adjeiwaa-Manu: Background on OMUFA and proposed OMUFA recommendations.

16
00:01:41.400 --> 00:01:46.060
Nana Adjeiwaa-Manu: This meeting is an opportunity for FDA to listen to public perspectives.

17
00:01:46.160 --> 00:01:51.640
Nana Adjeiwaa-Manu: Please note that FDA will not ask questions nor answer questions raised at this meeting.

WEBVTT

1
00:00:00.030 --> 00:00:09.669
Nana Adjeiwaa-Manu: Also, please keep in mind that you can submit electronic or written comments to a public docket that will be open until December 20 2024.

2
00:00:09.810 --> 00:00:15.159
Nana Adjeiwaa-Manu: We encourage everyone to submit their perspectives to the public docket for FDA Review.

3
00:00:15.260 --> 00:00:22.260
Nana Adjeiwaa-Manu: You can submit formal comments to the public docket by clicking on the green button at the top of the Federal Register notice.

4
00:00:22.570 --> 00:00:25.040
Nana Adjeiwaa-Manu: And now for a few housekeeping items.

5
00:00:25.230 --> 00:00:39.290
Nana Adjeiwaa-Manu: This public meeting is being conducted as hybrid, so some speakers will be participating virtually. We thank all the speakers for their efforts to prepare for this meeting, and we thank participants who are viewing remotely for your patience.

6
00:00:39.650 --> 00:00:46.110
Nana Adjeiwaa-Manu: If your audio or visual connection diminishes, we recommend trying to reconnect through the system.

7
00:00:46.290 --> 00:00:52.160
Nana Adjeiwaa-Manu: And if you experience any other technical issues during the Webcast. Please email Genevieve Huss.

8
00:00:52.220 --> 00:00:55.390
Nana Adjeiwaa-Manu: She will put her contact information in the webinar.

9
00:00:55.790 --> 00:00:59.100
Nana Adjeiwaa-Manu: We will have a 10 minute break at about 9:50.

10
00:00:59.110 --> 00:01:06.479
Nana Adjeiwaa-Manu: If schedule modifications are needed due to technical issues, we will communicate those verbally and show them on the screen.

11
00:01:07.110 --> 00:01:20.520
Nana Adjeiwaa-Manu: For those of you who are attending the meeting in person, there are restroom facilities available down the hall to the right of the conference room. Also, if you need water, we ask that you please take one of the water bottles that are just outside the doors.

12
00:01:21.510 --> 00:01:34.670
Nana Adjeiwaa-Manu: And then finally, for press inquiries, we ask that you contact Sherry Duval Jones, and she is in the Office of Media Affairs. Please note that her contact information is available on this slide.

13
00:01:35.240 --> 00:01:44.100
Nana Adjeiwaa-Manu: A video recording and transcription of today's meeting as well as the slides presented will be published on the FDA website after this meeting.

14
00:01:44.220 --> 00:01:51.450
Nana Adjeiwaa-Manu: And now I'll turn it over to Teresa Michele, Director of the Office of Non-prescription Drugs in CDER for her remarks.

15
00:02:15.300 --> 00:02:35.829
Teresa Michele: So welcome again, everyone as you heard from Dr. Cavazzoni, we're we're here today to obtain public input on the negotiated reauthorization recommendations for the second iteration of OTC monograph reform, or OMUFA, which was put in place four years ago by the Cares Act.

16
00:02:36.170 --> 00:02:50.290
Teresa Michele: So the first five-year cycle of OMUFA, as you heard, ends on September 30th of next year, at which point the program will need to be reauthorized by Congress in order to continue for future fiscal years.

17
00:02:50.510 --> 00:02:59.570
Teresa Michele: So the purpose of the reauthorization is really just to provide an opportunity to apply lessons learned from previous cycles

18

00:02:59.640 --> 00:03:09.120
TELEPHONE_USER: to the new cycle. And as it does with other user fee programs, FDA is required to negotiate

WEBVTT

1
00:00:00.230 --> 00:00:07.759
Teresa Michele: with industry about desired enhancements to the program to develop recommendations for reauthorization.

2
00:00:07.920 --> 00:00:13.929
Teresa Michele: These recommendations are captured in the proposed commitment letter, which is available on our website.

3
00:00:14.860 --> 00:00:19.150
Teresa Michele: Importantly, the focus of negotiations

4
00:00:19.410 --> 00:00:22.399
Teresa Michele: is on program enhancement,

5
00:00:23.200 --> 00:00:26.340
Teresa Michele: timelines for review, and resources.

6
00:00:26.790 --> 00:00:35.259
Teresa Michele: FDA does not discuss nor negotiate on specific policy positions as part of negotiations.

7
00:00:39.260 --> 00:00:53.369
Teresa Michele: So OTC monograph reform helped increase the efficiency, timeliness, and predictability of OTC monograph drug regulation. It encouraged innovation and streamlined safety updates.

8
00:00:54.740 --> 00:01:12.040
Teresa Michele: This change was accompanied by providing FDA the authority to collect user fees to support OTC. Monograph drug activities, and these, of course, provide vital resources to allow us to meet the negotiated timelines and performance goals.

9
00:01:13.590 --> 00:01:16.740
Teresa Michele: As you heard, these changes just really

10
00:01:16.760 --> 00:01:21.899
Teresa Michele: provide an exciting new chapter in OTC drug history.

11
00:01:22.050 --> 00:01:39.569
Teresa Michele: The Cares Act addressed serious process weaknesses under the former OTC. Drug Review, including the burdensome multi-step rulemaking process. It often took many years to get a rule out to address even a minor safety change.

12
00:01:40.160 --> 00:01:43.699
Teresa Michele: It addressed limitations on innovations

13
00:01:44.070 --> 00:01:46.580
Teresa Michele: and inadequate resources.

14
00:01:47.090 --> 00:01:53.770
Teresa Michele: So, guided by input from industry, consumer, patient and professional groups.

15
00:01:53.880 --> 00:01:58.700
Teresa Michele: OMUFA reauthorization helps ensure those continued benefits.

16
00:02:01.940 --> 00:02:21.330
Teresa Michele: OMUFA, one has been incredibly successful in meeting the goals set out in the user fee document as well as the statutory requirements. So, for example, we've got several new I.T. systems in place that provide a 1-stop shop for both industry and the public, for all things monograph.

17
00:02:21.840 --> 00:02:34.680
Teresa Michele: We have an annual forecast of activities that we're anticipating conducting over the next three years. We have a slew of draft guidances which I'm not going to read through right now,

18
00:02:34.740 --> 00:02:37.079
Teresa Michele: and the heaviest lift of all.

19
00:02:37.180 --> 00:02:40.820
Teresa Michele: We have thirty-three deemed final orders

20
00:02:40.860 --> 00:02:59.560
Teresa Michele: that put the baseline monographs as set forth by Congress in place. So, both industry and FDA can consider what changes might be needed, and allow industry an easy system that they can follow when they bring their monograph drugs to market.

21
00:03:00.630 --> 00:03:07.300
Teresa Michele: I'm also very proud that we have exceeded all of the timelines for meeting management goals.

22
00:03:07.540 --> 00:03:17.829
Teresa Michele: And this refers to formal meetings between industry and FDA to discuss OTC drug development programs.

23
00:03:18.770 --> 00:03:21.720
Teresa Michele: It's really exciting to see these come in.

24
00:03:21.740 --> 00:03:34.439
Teresa Michele: Because before monograph reform, four years ago, these meetings didn't exist, we had no mechanism to talk about innovation. And in fact, innovation didn't really exist very much.

25
00:03:35.180 --> 00:03:40.339
Teresa Michele: And so ,it's perhaps a good moment to just pause and think about that context.

26
00:03:40.590 --> 00:03:45.189
Teresa Michele: Because, as you heard again from Dr. Cavazzoni,

27
00:03:45.860 --> 00:03:51.739
Teresa Michele: we weren't just putting timelines into an existing regulatory structure.

28
00:03:51.950 --> 00:03:58.840
Teresa Michele: We've actually been creating the infrastructure from the ground up for a whole new program

29
00:03:58.880 --> 00:04:01.359
Teresa Michele: that was given to us by Congress.

30
00:04:01.630 --> 00:04:02.620
Teresa Michele: And uh,

WEBVTT

1
00:00:00.000 --> 00:00:06.950
Teresa Michele: that comes with all of the accompanying new questions, new issues to be addressed.

2
00:00:07.070 --> 00:00:13.619
Teresa Michele: So it's a big lift, and I'm excited to see the progress that's been made.

3
00:00:14.550 --> 00:00:23.840
Teresa Michele: So over the last year, we also have a number of firsts that represent real progress in advancing public health goals, safety and innovation under the program.

4
00:00:24.010 --> 00:00:26.559
Teresa Michele: So, for example, in June

5
00:00:26.570 --> 00:00:37.710
Teresa Michele: FDA issued its first FDA initiated Safety Order addressing a safety issue related to Acetaminophen serious skin reactions.

6
00:00:38.690 --> 00:00:44.080
Teresa Michele: Now, we started communicating about this issue way back in 2013,

7
00:00:44.100 --> 00:00:49.189
Teresa Michele: very long time ago, in terms of thinking about a safety issue like that

8
00:00:49.260 --> 00:01:01.569
Teresa Michele: We issued a drug safety communication informing the public that Acetaminophen could be associated with rare but serious skin reactions.

9
00:01:02.040 --> 00:01:09.570
Teresa Michele: Now, because the process for modifying the monograph was sort of bogged down in the Federal rulemaking process.

10
00:01:09.640 --> 00:01:13.880
Teresa Michele: In 2017 we issued a guidance

11
00:01:14.490 --> 00:01:19.389
Teresa Michele: which encouraged industry to add this warning to their label.

12

00:01:19.760 --> 00:01:27.730
Teresa Michele: However, as we all recognize this was an incredibly suboptimal way to regulate OTC drugs.

13
00:01:28.190 --> 00:01:46.329
Teresa Michele: And so, when Dr. Woodcock was asked to testify before the House E&C Committee on Monograph Reform. She literally had two bottles of Acetaminophen. I purchased these myself from the grocery store, and they were sitting right next to each other on the shelf.

14
00:01:46.670 --> 00:01:51.959
Teresa Michele: She held one up that had the label and one that didn't.

15
00:01:52.690 --> 00:02:00.370
Teresa Michele: And so, during the hearing, this was really the poster child, and the example of why we needed monograph reform.

16
00:02:00.410 --> 00:02:09.480
Teresa Michele: So it's just incredibly gratifying to me personally to see this order come out and see this come full circle.

17
00:02:09.680 --> 00:02:13.999
Teresa Michele: So that we are starting to really realize the promise

18
00:02:14.010 --> 00:02:16.330
Teresa Michele: of OTC monograph reform.

19
00:02:17.830 --> 00:02:25.110
Teresa Michele: In addition to this big first, we also took a step forward to address pediatric cough cold

20
00:02:25.250 --> 00:02:31.739
Teresa Michele: ingredients, and this was, of course, as directed by Congress as part of the Cares Act.

21
00:02:32.380 --> 00:02:36.999
Teresa Michele: So this order came out just a few months ago

22
00:02:37.290 --> 00:02:45.199
Teresa Michele: which proposes to remove oral phenylephrine as a nasal decongestant, because it is not efficacious.

23

00:02:46.950 --> 00:02:54.270
Teresa Michele: And finally, I'm excited to be able to report that we have our very 1st OTC monograph order request, or OMOR.

24
00:02:54.420 --> 00:02:58.319
Teresa Michele: And because the company made it public,

25
00:02:58.350 --> 00:03:02.909
Teresa Michele: I can tell you that this 1st OMOR would, if

26
00:03:03.040 --> 00:03:07.359
Teresa Michele: authorized, add a new sunscreen ingredient to the monograph.

27
00:03:07.700 --> 00:03:14.270
Teresa Michele: And we're, of course, reviewing that submission under the timelines established in the first user fee goals document.

28
00:03:16.740 --> 00:03:24.840
Teresa Michele: So this slide shows the statutory language related to reauthorization of OMUFA.

29
00:03:24.900 --> 00:03:33.440
Teresa Michele: And it's exciting that we are now at one of the last steps in the reauthorization process with this public meeting.

30
00:03:35.340 --> 00:03:48.870
Teresa Michele: Looking at the process a different way, this gives you a timeline of it, and you can see this began over a year ago with a public announcement, followed by a public meeting. About this time last year

31
00:03:49.340 --> 00:03:57.999
Teresa Michele: when we began gathering feedback on the topics that we should consider with industry for negotiations.

32
00:03:58.200 --> 00:04:02.200
Teresa Michele: And then, of course, the negotiation process itself.

33
00:04:02.470 --> 00:04:10.899
Teresa Michele: and we're nearing now the statutory deadline to submit those recommendations to Congress by January 15.

34

00:04:11.710 --> 00:04:26.889
Teresa Michele: We especially appreciate the time and effort put into the process by negotiated industry to help come up with these set of recommendations and enhancements to the program.

35
00:04:26.900 --> 00:04:31.809
Teresa Michele: And these recommendations were ratified by both industry and FDA.

36
00:04:32.610 --> 00:04:45.699
Teresa Michele: Once again, we look forward now to receiving public comment from all of you, and I'm including all of our virtual participants as well. And thank you for providing comments

37
00:04:45.800 --> 00:04:51.280
Teresa Michele: for the time you took to do that, and for those comments that you'll submit to the docket.

38
00:04:53.380 --> 00:05:03.280
Teresa Michele: So, with that I'll stop and turn you over to Dr. Karen Murray, who will start talking about the agreement.

39
00:05:16.900 --> 00:05:17.959
Karen Murray: Good morning.

40
00:05:18.390 --> 00:05:24.650
Karen Murray: I'll be giving a brief overview of some main points of the agreement reached between the industry and FDA negotiating teams.

41
00:05:32.390 --> 00:05:42.229
Karen Murray: The enhancements and vision for OMUFA II fall into seven categories. I'll introduce them in this slide, and then I and others will expand on them further as we go along.

42
00:05:42.290 --> 00:05:51.930
Karen Murray: First, education, including several commitments included to enhance Industry's understanding of how to navigate OTC monograph regulatory processes.

43
00:05:52.360 --> 00:05:58.259
Karen Murray: Second, commitments around quality surveillance and quality related information transparency.

44

00:05:58.510 --> 00:06:00.750
Karen Murray: Next, commitments to

45
00:06:01.580 --> 00:06:04.840
Karen Murray: address certain testing methods in existing monographs.

46
00:06:05.140 --> 00:06:10.219
Karen Murray: Next, adjusting the commitment letter, so that its language aligns with that of the statute.

47
00:06:10.660 --> 00:06:16.789
Karen Murray: There are also several commitments around meetings intended to improve efficiency and enhance communication.

48
00:06:17.000 --> 00:06:21.809
Karen Murray: Another commitment group supports information transparency and documentation.

49
00:06:21.860 --> 00:06:23.479
Karen Murray: And finally, they're enhancements

WEBVTT

1
00:00:00.000 --> 00:00:03.240
Karen Murray: to financial efficiency and transparency.

2
00:00:07.770 --> 00:00:14.430
Karen Murray: OTC monograph reform includes many regulatory processes that are new to both FDA and industry.

3
00:00:14.540 --> 00:00:19.369
Karen Murray: Several proposed commitments are intended to assist with navigation of these processes.

4
00:00:19.800 --> 00:00:24.499
Karen Murray: First, some Webinars are to be developed to assist external stakeholders.

5
00:00:24.740 --> 00:00:33.989
Karen Murray: For one FDA will use crowdsourcing to solicit stakeholder questions related to OMOR submissions and requirements for finalization of GRASE status.

6

00:00:34.310 --> 00:00:37.829
Karen Murray: FDA will then develop a webinar to address those questions.

7
00:00:38.480 --> 00:00:46.710
Karen Murray: There is to be a draft guidance to assist with understanding confidentiality as it pertains to OTC monograph information submitted to FDA.

8
00:00:47.760 --> 00:00:59.740
Karen Murray: Under the statute, when a requestor proposes a new monograph active ingredient, FDA must determine whether that ingredient meets certain eligibility requirements before the OMOR could be filed.

9
00:01:00.130 --> 00:01:07.650
Karen Murray: FDA is to develop a draft guidance about those eligibility requirements and the implementation of this part of the filing process.

10
00:01:12.220 --> 00:01:15.410
Karen Murray: Several commitments pertain to manufacturing quality.

11
00:01:15.820 --> 00:01:31.860
Karen Murray: First, regarding quality surveillance enhancement. There is a commitment to vet new monograph registrants within six months of registration, which will help FDA more quickly gain accurate information from registrants as we plan for manufacturing facility inspections.

12
00:01:32.670 --> 00:01:45.860
Karen Murray: FDA will also update CDERs risk-based site selection model to include monograph related risk factors for potential quality problems and will develop a related map which is a policy and procedures document.

13
00:01:46.100 --> 00:01:57.639
Karen Murray: The site selection model helps FDA to prioritize which manufacturing facilities are subject to a routine surveillance inspection to evaluate compliance with current good manufacturing practice.

14
00:01:58.590 --> 00:02:06.010
Karen Murray: FDA will hold a workshop to assist industry in improving quality and compliance with current good manufacturing practices

15
00:02:06.480 --> 00:02:14.970

Karen Murray: Regarding transparency, FDA will issue annual reporting on records requests issued to monograph drug manufacturers.

16
00:02:15.240 --> 00:02:21.529
Karen Murray: FDA can use a formal records request to gain information about a manufacturer's compliance with CGMP.

17
00:02:21.990 --> 00:02:29.859
Karen Murray: As part of this commitment FDA would share aggregate information about the types of records we've requested and the outcomes of our assessment of those records.

18
00:02:30.480 --> 00:02:36.310
Karen Murray: FDA will also enhance the web page regarding warning letters to improve search capability.

19
00:02:36.660 --> 00:02:39.390
Karen Murray: This enhancement would make it easier for interested parties

WEBVTT

1
00:00:00.000 --> 00:00:04.719
Karen Murray: to locate warning letters issued to facilities manufacturing OTC monograph products.

2
00:00:08.940 --> 00:00:18.779
Karen Murray: Some existing monographs include specific information about appropriate test methods to be used. There are two enhancements proposed in this area.

3
00:00:18.850 --> 00:00:21.800
Karen Murray: The first, we need a statutory change by Congress.

4
00:00:21.810 --> 00:00:26.449
Karen Murray: In the existing statutory language there are two tiers of OMORs with different fees.

5
00:00:26.650 --> 00:00:36.770
Karen Murray: Tier two OMORs which have a lower fee than tier one. OMORs are a defined set of submissions expected to require fewer review resources than the more complex tier one OMORs.

6
00:00:37.250 --> 00:00:46.550

Karen Murray: the negotiating team is recommending addition of a new type of tier two OMOR proposing the addition or modification of certain test methods in a monograph.

7
00:00:46.820 --> 00:01:00.990
Karen Murray: These new proposed testing methods would need to reflect a voluntary consensus standard for pharmaceutical quality established by a national or international standards development organization recognized by FDA.

8
00:01:01.880 --> 00:01:10.010
Karen Murray: FDA will also issue a Federal Register Notice and conduct crowdsourcing, soliciting feedback on existing test methods and monographs.

9
00:01:13.290 --> 00:01:21.820
Karen Murray: Prior to passage of the Cares Act, industry and FDA had extensive discussions on what monograph reform and user fee commitments might look like.

10
00:01:22.340 --> 00:01:29.730
Karen Murray: These discussions resulted in a goals document that was submitted about three years prior to the actual passage of Cares.

11
00:01:30.170 --> 00:01:39.049
Karen Murray: Since FDA could not know exactly what language would go into the statute, there are naturally some areas of non-alignment between that goals document and the statute.

12
00:01:39.420 --> 00:01:43.949
Karen Murray: The OMUFA II draft commitment letter is written to be in alignment with the statute.

13
00:01:44.130 --> 00:01:48.299
Karen Murray: Examples of updates include eligibility language.

14
00:01:48.510 --> 00:01:54.609
Karen Murray: You recall that I spoke a few moments ago about eligibility determination for new monograph ingredients.

15
00:01:54.740 --> 00:02:00.040
Karen Murray: The original Goals letter envisioned that determination occurring before OMOR submission.

16

00:02:00.050 --> 00:02:08.079
Karen Murray: but the statute specifies that eligibility determination is to occur after OMOR submission, and before filing.

17
00:02:08.600 --> 00:02:15.100
Karen Murray: The prior timing had not included sufficient time to do this. So the new commitment adds this time.

18
00:02:15.660 --> 00:02:28.409
Karen Murray: regarding major amendments. The original goals document discussed the possibility of amendment submission after issuance of a proposed order, but that is not compatible with the necessary opportunity for public comment.

19
00:02:28.480 --> 00:02:34.700
Karen Murray: So the OMUFA II commitment letter does not provide for review of a major amendment submitted after a proposed order.

20
00:02:35.680 --> 00:02:42.040
Karen Murray: Regarding the public comment period after a proposed order. The existing statute includes the possibility of comment.

WEBVTT

1
00:00:00.490 --> 00:00:05.520
Karen Murray: And the proposed commitment letter provides for a corresponding final goal date extension.

2
00:00:05.900 --> 00:00:11.180
Karen Murray: Thank you. And I'll now pass it over to Paul Phillips for information on other proposed enhancements.

3
00:00:22.140 --> 00:00:23.900
Paul Phillips: Thank you so much, Dr. Murray.

4
00:00:24.530 --> 00:00:42.910
Paul Phillips: As Dr. Murray said my name is Paul Phillips. I'm the Director of the Office of Program Operations in CDERs Office of New Drugs. And I'm going to present today some proposed changes that impact two primary areas. The first is meetings, and the second is information transparency, and documentation. As was previously stated.

5
00:00:44.330 --> 00:01:02.089

Paul Phillips: First, I'll touch on the changes impacting meetings in the area of meetings. These changes primarily impact two categories of meetings. The first is formal meetings between industry and the FDA. These are captured in the commitment letter under Type X, Y, and Z meetings.

6
00:01:02.430 --> 00:01:20.879
Paul Phillips: The second category of meetings that the proposed changes impact are our public advisory committee meetings. So I'll begin with the changes related to and impacting formal meetings between industry and the FDA. The first change is related to an update or a proposed update to the definition of a face-to-face meeting.

7
00:01:21.060 --> 00:01:33.979
Paul Phillips: This proposal is in order to align the commitment or excuse me to align the definition of a face-to-face meeting in the OMUFA commitment letter with the definition as it now exists in other major user fee commitment letters.

8
00:01:37.736 --> 00:01:43.460
Paul Phillips: The proposed change specifically, this is what happens when you're tall. You need a microphone that's taller.

9
00:01:43.640 --> 00:02:07.020
Paul Phillips: The proposed change to the update specifically would be to include not only meetings where we're in person face-to-face in the room together, but also to include virtual meetings with cameras on. So you can literally see one another's faces as you're discussing during the meetings. The other benefit or reason for this change is to capture efficiencies of virtual meetings that were realized during the pandemic era.

10
00:02:07.140 --> 00:02:29.629
Paul Phillips: The second proposed change impacts, or is rather a clarification about the length of meetings. Typically meetings, formal meetings specifically between the Agency and industry are about one hour in length. And this would clarify that when there's complex topics to be discussed, industry could request a longer timeline, and those would be considered by the Agency under appropriate circumstances.

11
00:02:30.120 --> 00:02:36.019
Paul Phillips: The next change is a specification about how meetings are to be submitted, the meeting request specifically.

12
00:02:36.140 --> 00:02:51.390

Paul Phillips: They would be submitted through the CDERs Next Gen Portal instead of by email. The intent of this change is to increase the fidelity and also the efficiency with which the Agency can track and respond and handle those meeting requests.

13
00:02:52.150 --> 00:03:05.829
Paul Phillips: The next change is related to a new mechanism of communication between industry and FDA. Specifically intended to help ensure that advice provided by the Agency to industry is understood.

14
00:03:05.880 --> 00:03:32.219
Paul Phillips: So when that advice is provided in the form of either meeting minutes or a written response only, when either of those two is received by industry, industry can then, within a specified time frame, send in questions of a clarifying nature. The Agency would then respond back to those questions on a specific time frame, and either confirm understanding of industry or provide additional written information to ensure an understanding of the points in question.

15
00:03:33.100 --> 00:03:42.239
Paul Phillips: The next change and the final change related to formal meetings is tied to clarifying how industry can receive feedback on protocol synopses.

16
00:03:42.470 --> 00:03:46.769
Paul Phillips: So that can happen in the context of a formal meeting request as well.

17
00:03:46.800 --> 00:04:02.479
Paul Phillips: Either when there is other items in a meeting request that would qualify for a type Y meeting. The protocol synopses can be submitted with that, or if the intent is just to receive feedback on the protocol synopses alone that can be submitted as a type Z meeting.

18
00:04:03.560 --> 00:04:14.489
Paul Phillips: One point that I'll make here is this is very specific to protocol synopses and not full protocol review, which is a little bit larger than is appropriate for the timelines of a formal meeting.

19
00:04:14.910 --> 00:04:23.089
Paul Phillips: The last change then related to meetings is for Advisory Committee meetings or public meetings, and specifically in this case, OTC related meetings.

20
00:04:23.290 --> 00:04:43.629

Paul Phillips: This is a commitment that the Agency would make with regard to advance notice of an anticipated Advisory Committee meeting for a certain subset of OTC. Related Advisory Committee meetings. Meaning those that are not intended to address an emerging safety issue, or already fall within the scope of our existing Advisory Committee meeting guidance

21
00:04:43.720 --> 00:04:58.810
Paul Phillips: Specifically, the commitment would be to provide this public notice via our website 100 days in advance of that meeting, and the intent there is to provide sufficient time for impacted stakeholders to prepare for, and then meaningfully engage.

WEBVTT

1
00:00:00.020 --> 00:00:02.490
Paul Phillips: Agency during that public meeting.

2
00:00:07.260 --> 00:00:09.960
Paul Phillips: And it looks like the advancer is not working.

3
00:00:15.130 --> 00:00:16.799
Paul Phillips: So next slide, if we could.

4
00:00:21.630 --> 00:00:23.100
Paul Phillips: Alright. Thank you so much.

5
00:00:23.710 --> 00:00:30.139
Paul Phillips: All right. The last set of proposed changes I'm going to cover are related to information transparency and documentation.

6
00:00:30.860 --> 00:00:46.979
Paul Phillips: There's three primary changes in this area. The first is related to exclusivity for those of you that don't know the OTC monograph statute affords exclusivity when the Agency issues a final order for certain types of final orders as requested.

7
00:00:46.980 --> 00:01:07.450
Paul Phillips: I'm not going to go into detail on those, but, needless to say, we have learned that there are certain pieces of information that are valuable to external stakeholders to be made aware of. And so this commitment pertains to the Agency creating a website where we would list the monograph change that's the subject of the final order. The requesters who requested that change,

8

00:01:07.700 --> 00:01:14.269
Paul Phillips: the final order, date, or the date on which the Agency took that action, and, lastly, the date of the update

9
00:01:14.320 --> 00:01:17.120
Paul Phillips: for the relevant EDRLS listing.

10
00:01:17.380 --> 00:01:22.879
Paul Phillips: These could then be used by external stakeholders as needed, as it pertains to exclusivity.

11
00:01:23.470 --> 00:01:27.550
Paul Phillips: The next change has to do with historical paper documents.

12
00:01:27.600 --> 00:01:38.559
Paul Phillips: They contain a lot of information related to OTC Monograph ingredients, and review of those. Many of these documents are very old and very fragile, and not easily accessible.

13
00:01:38.680 --> 00:01:48.400
Paul Phillips: There is a commitment as a part of the current iteration of OMUFA, OMUFA I, one where the agency is documenting each of those individual documents

14
00:01:48.440 --> 00:02:12.280
Paul Phillips: by creating an online database of those just acknowledging that they exist, and which monograph ingredient is discussed within the documents. But that commitment does not include making the substance of those documents available. So this proposal is to take the next step and to scan each of those paper documents and then put them in a public document and link them to the

15
00:02:12.320 --> 00:02:31.649
Paul Phillips: to the database that's being created as part of the catalog that's being created as a part of the OMUFA I commitment thereby creating a much richer resource that is publicly accessible and searchable. As you can anticipate, that would be useful in external stakeholders considering potential future proposed changes to monographs.

16
00:02:32.830 --> 00:03:00.569
Paul Phillips: The last change is related to also historical preservation of information, and this is tied to the Agency's existing historical status of OTC rulemaking's website. And for those that may not be familiar with this website, it's actually a very extensive website with links to Federal Register notices pertaining to the Agency's historical

rulemaking for a vast number of monograph related therapeutic subcategories.

17
00:03:00.570 --> 00:03:28.189
Paul Phillips: We've learned and found that that information is also valuable to external entities as they consider future potential changes to monographs as they look to the past. To understand FDA's historical thinking when those monographs were created. So the commitment here would be simply to maintain that website in its current form, and ensure that all of the links that are in there to those Federal Register documents are retained in perpetuity and made accessible to the public for searching.

18
00:03:28.550 --> 00:03:34.050
Paul Phillips: And with that that concludes the changes that I'll cover today, and I'll turn the time now to my colleague, Angela Granum.

19
00:03:42.940 --> 00:03:54.369
Angela Granum: Thank you. My name is Angela Graham. I'm the Division Director for the Division of User Fee Management. I'm going to talk about some of the changes related to financial transparency and efficiency.

20
00:03:56.920 --> 00:04:14.520
Angela Granum: So the first major change that we are proposing is related to the facility fee due date. We're proposing a statutory revision to change the facility fee due date from June 1 of the fiscal year to October 1, which is the start of our Federal fiscal year.

21
00:04:14.520 --> 00:04:28.769
Angela Granum: This change will align with the due date for the annual fees under other user fee programs, and we believe that it will identify, or it will address some of the inefficiencies, both administratively and financially, that are stemming from the current due date.

22
00:04:29.320 --> 00:04:39.409
Angela Granum: We're transitioning in 2027 and the fees in that year will be due in two installments in order to address some of the cash flow concerns the industry expressed.

23
00:04:39.480 --> 00:04:53.320
Angela Granum: Transitioning in the second year of OMUFA II will allow us to have ample time after reauthorization, to communicate these changes to industry and ensure that everyone is prepared and knows what the expectation will be around the the new fee due date.

24
00:04:53.790 --> 00:05:20.550

Angela Granum: Finally, we have a nine month fee liability period in the transition year in order to ensure that facilities wouldn't be liable for two annual fees based on operations in a single three month period. So again, we'll communicate that with industry to make sure that everyone understands those changes in liability period, and when they need to register and deregister in order to avoid liability for a given fiscal year, if necessary.

25
00:05:21.240 --> 00:05:41.809
Angela Granum: The second change here again, is a proposed statutory addition to make a one-time adjustment in the calculation for target revenue, based on the average number of fee liable facilities exceeding 1625 in certain years of a OMUFA II. If the average percentage of those facilities in arrears is under 30%.

26
00:05:42.160 --> 00:05:49.050
Angela Granum: That adjustment would help FDA to accommodate additional work required to oversee growth in the number of facilities.

27
00:05:49.080 --> 00:06:00.179
Angela Granum: If this adjustment is made, it would be part of our base revenue going forward. And again, that adjustment would only be made one time, if at all during the OMUFA II authorization period.

28
00:06:00.370 --> 00:06:14.129
Angela Granum: Based on what we are currently seeing in the number of facilities we don't anticipate the need for this adjustment, but it does help guard against any potential volatility in the number of manufacturers during the OMUFA II authorization period.

29
00:06:17.450 --> 00:06:33.640
Angela Granum: The next set of changes is around visibility for the arrears list. The commitments include information to highlight arrears list information in a number of different ways. We would also utilize records request information in order to focus our fee recovery efforts.

30
00:06:33.800 --> 00:06:51.080
Angela Granum: In addition to the existing arrears list information that we already publish on our website FDA has committed to publishing a list of facilities that have satisfied their fees for each fiscal year. We would also publish summary registration and arrears information in our annual OMUFA financial reports.

31
00:06:52.190 --> 00:07:05.390
Angela Granum: Finally, the proposed package includes a proposal to reset the base revenue for OMUFA II to include the 3 million dollar additional direct cost adjustment from the final year of OMUFA I.

32
00:07:05.520 --> 00:07:17.550
Angela Granum: This change would not result in any year-on-year increase in revenue, but it would ensure continued funding to support the important investments that were made in infrastructure during OMUFA I that my colleagues have already discussed.

33
00:07:18.100 --> 00:07:20.640
Angela Granum: And with that I'll turn it back over to our moderator.

34
00:07:29.230 --> 00:07:30.789
Nana Adjeiwaa-Manu: Thank you, Ms. Granuum.

35
00:07:31.110 --> 00:07:55.700
Nana Adjeiwaa-Manu: Now we will take a brief break before continuing on to the stakeholder panel sessions. We will reconvene promptly at 10:00am. Just a few notes here. The kiosk is open just outside of the doors to your right for coffee. Also the restrooms are available outside the doors down the hall to the right of the conference room. And lastly, if you need water when you go outside the doors. There are bottles available. Thank you,

36
00:08:03.170 --> 00:08:04.630
Nana Adjeiwaa-Manu: As a reminder,

37
00:08:05.660 --> 00:08:13.819
Nana Adjeiwaa-Manu: if you experience technical issues during the webcast, please email Genevieve Huss, whose email is provided in the Webinar.

38
00:08:13.940 --> 00:08:21.089
Nana Adjeiwaa-Manu: Also, please keep in mind that you can submit comments to a public docket that will be open until December 20.

39
00:08:21.220 --> 00:08:27.030
Nana Adjeiwaa-Manu: We encourage everyone to submit their perspectives to the public docket for FDA review.

40
00:08:27.330 --> 00:08:34.620
Nana Adjeiwaa-Manu: You can submit formal comments to the public docket by clicking on the green button at the top of the Federal Register notice.

41
00:08:35.070 --> 00:08:41.539
Nana Adjeiwaa-Manu: Before the break we learned more about the key features of the proposed OMUFA II recommendations.

42
00:08:41.820 --> 00:08:45.339
Nana Adjeiwaa-Manu: We will now move into the stakeholder panel sessions.

43
00:08:45.510 --> 00:08:50.549
Nana Adjeiwaa-Manu: To keep the meeting moving forward on time, I will announce when there is one minute left.

44
00:08:50.810 --> 00:08:56.140
Nana Adjeiwaa-Manu: At the 10 minute mark I will ask you to conclude and then introduce the next speaker.

45
00:09:01.590 --> 00:09:06.799
Nana Adjeiwaa-Manu: The clicker is not quite working the way I'd like it to. Let's see if I can get it here.

46
00:09:07.740 --> 00:09:13.760
Nana Adjeiwaa-Manu: Okay, that is okay. Our first panel is on regulated industry perspectives.

47
00:09:13.930 --> 00:09:16.380
Nana Adjeiwaa-Manu: We have 6 speakers in this section.

48
00:09:16.640 --> 00:09:29.839
Nana Adjeiwaa-Manu: Mike Bailey from the Consumer Health Care Products Association. Dan Selechnik, who is from the Fragrance Creators Association, Gil Roth, who is from the Pharma and Biopharma Outsourcing Association.

49
00:09:29.980 --> 00:09:34.069
TELEPHONE_USER: Emily Manoso, who is from the Personal Care Products Council.

50
00:09:34.090 --> 00:09:42.040
Nana Adjeiwaa-Manu: James Kim, who is from the American Cleaning Institute, and Meredith Petillo, who is from the Independent Beauty Association.

51
00:09:42.120 --> 00:09:46.080

Nana Adjeiwaa-Manu: Mike, as our first speaker in this session. You may begin.

52
00:09:53.200 --> 00:09:55.359
Mike Bailey: Thank you. And it's good to be here.

53
00:09:56.760 --> 00:10:18.039
Mike Bailey: good morning. I'm Michael Bailey, senior Vice President of Regulatory and Scientific Affairs at Consumer Health Care Products Association or CHPA, and we appreciate the opportunity to address today's meeting. I won't be using slides, so don't worry about the clicker. CHPA represents the leading manufacturers and marketers of OTC Medicines.

54
00:10:18.450 --> 00:10:27.669
Mike Bailey: and both CHPA and its members are firmly committed to working with FDA to ensure prompt and effective implementation of monograph reform.

55
00:10:28.220 --> 00:10:55.840
Mike Bailey: CHPA and its members also recognize that over-the-counter monograph user fee program or OMUFA is central to the success of monograph reform and that a well-designed OMUFA program should provide FDA with adequate resources to implement the OTC Monograph review program, while also ensuring that industry and other stakeholders receive the guidance, feedback, and other support necessary

56
00:10:55.880 --> 00:11:00.030
Mike Bailey: to advance key innovations in the OTC drug market.

57
00:11:01.110 --> 00:11:20.200
Mike Bailey: Before discussing key points in the OMUFA II reauthorization cycle, CHPA would like to 1st acknowledge the steps FDA has already taken to implement monograph reform and carry out its original OMUFA I commitments since OMUFA was 1st authorized in 2020.

58
00:11:20.370 --> 00:11:25.540
Mike Bailey: 1st conversion of most OTC Monographs to deemed final orders.

59
00:11:25.680 --> 00:11:30.780
Mike Bailey: Next, the issuance of several guidance documents, both final and draft.

60
00:11:31.150 --> 00:11:40.250

Mike Bailey: Third, significant infrastructure was put in place, including websites, NextGen portal, hiring of staff, and collection of fees.

61
00:11:41.020 --> 00:11:48.320
Mike Bailey: Fourth, meeting with regulatory industry to discuss innovations and GRASE finalizations. Those meetings are occurring.

62
00:11:48.720 --> 00:11:56.790
Mike Bailey: And finally, the issuance of the 1st initiated Safety Order regarding labeling for analgesics, as it has been mentioned already this morning.

63
00:11:56.900 --> 00:12:06.270
Mike Bailey: We look forward to FDA's finalization of OMUFA I commitments, including draft guidance on minor changes to solid oral dosage drugs.

64
00:12:06.400 --> 00:12:14.929
Mike Bailey: Guidance from FDA on these and other important topics will be essential resource as the industry navigates the monograph review process.

65
00:12:15.990 --> 00:12:17.010
Mike Bailey: So

66
00:12:17.340 --> 00:12:21.319
Mike Bailey: as we initiated the move for reauthorization process

67
00:12:21.390 --> 00:12:30.859
Mike Bailey: we wanted to advance our shared goal of unlocking key innovations in the OTC drug market while upholding rigorous safety and efficacy standards.

68
00:12:31.460 --> 00:12:44.309
Mike Bailey: In this spirit CHPA would like to highlight four key points that we believe will play a central role in ensuring the success of OTC monograph reform as we move into the OMUFA II cycle.

69
00:12:44.770 --> 00:12:50.329
Mike Bailey: First, OMUFA needs to remain a lean and efficient program.

70
00:12:50.370 --> 00:12:58.939

Mike Bailey: OMUFA II will add 11 FTEs, supporting the OTC monograph system for a total of 112 FTEs.

71
00:12:59.130 --> 00:13:04.390
Mike Bailey: We see this as nearing the maintenance level in terms of staffing and paid fees

72
00:13:04.430 --> 00:13:17.249
Mike Bailey: and we believe that the current model of funding OMUFA with facility fees where manufacturers pay fees is the right choice for this UFA. Although this does differ from some other UFAs.

73
00:13:17.980 --> 00:13:19.030
Mike Bailey: Second.

74
00:13:19.080 --> 00:13:24.830
Mike Bailey: interactions between industry and FDA are critical to the success of the program.

75
00:13:24.910 --> 00:13:35.220
Mike Bailey: We've seen FDA increase the number of in-person or virtual meetings versus WROs, and we support this and the benefit of in-person dialogue.

76
00:13:35.540 --> 00:13:44.219
Mike Bailey: OMUFA meetings often require lengthy scientific dialogue due to the long history of the monograph and data supporting them.

77
00:13:44.520 --> 00:13:58.279
Mike Bailey: Recognizing this may require meetings longer than the traditional 1 h and allow for follow-up opportunities or important improvements in OMUFA II goals letter that will facilitate scientific dialogue.

78
00:13:59.220 --> 00:14:00.430
Mike Bailey: Third

79
00:14:00.550 --> 00:14:08.749
Mike Bailey: innovation must be supported in a manner that maintains GRASE standards for the foundation of the OTC monograph system.

80
00:14:09.340 --> 00:14:19.710

Mike Bailey: Monograph reform did not change the substantive standard FDA must apply when making general recognition of safety and effectiveness or GRASE determinations.

81
00:14:20.090 --> 00:14:28.270
Mike Bailey: Under this standard GRASE determination should be based principally on reports of the relevant studies in the published literature.

82
00:14:28.690 --> 00:14:36.769
Mike Bailey: The relevant regulations are consistent with GRASE concept as applied by FDA in the courts over many decades.

83
00:14:37.640 --> 00:14:48.290
Mike Bailey: In addition, section 505(g) of The Federal Food and Cosmetic Act Congress made clear that its intent was to maintain the substantive standards for GRASE determinations.

84
00:14:48.510 --> 00:15:02.819
Mike Bailey: FDA acknowledged this in its June 23rd draft guidance on the formal dispute resolution and administrative hearings of final administrative orders under section 505(g). Where it confirmed that general recognition of safety and effectiveness

85
00:15:02.930 --> 00:15:14.409
Mike Bailey: requires, among other things, the information demonstrating that a drug is safe and effective for its intended use to be published, so that information is generally available to qualified experts.

86
00:15:14.840 --> 00:15:30.430
Mike Bailey: Although section 505(g) Requires FDA to withdraw certain regulations governing the procedures for OTC Drug Review, it did not direct the agency to withdraw or modify the substantive requirements for GRASE determinations.

87
00:15:31.080 --> 00:15:42.989
Mike Bailey: As we move into the OMUFA II cycle, it is essential that FDA ground its review and the advice it provides during meetings and the review process in the long-established GRASE standard.

88
00:15:42.990 --> 00:15:54.520
Mike Bailey: In particular, it is essential that FDA affirm that GRASE determinations shall be based principally on the reports of relevant studies in the published literature. It will also be important for FDA to recognize

89
00:15:54.520 --> 00:16:13.770
Mike Bailey: the valuable role that real world evidence provides in supporting GRASE conclusions, including, for example, evidence showing lack of safety signal for drugs with a long marketing history, accepting new or updated test methods based on consensus standards via the OMOR process is another important OMUFA

90
00:16:13.980 --> 00:16:15.330
Mike Bailey: improvement

91
00:16:17.020 --> 00:16:32.040
Mike Bailey: applying GRASE standards, and GRASE determinations are not and should not be, dependent on an NDA-style submission and review. For example, it is well established that GRASE determinations in the non-prescription drug contexts

92
00:16:32.310 --> 00:16:38.529
Mike Bailey: assess the safety and efficacy of the active ingredient to be authorized under the applicable monograph.

93
00:16:38.630 --> 00:16:52.289
Mike Bailey: This does not involve the review of inactive ingredients which can vary between products authorized under a single monograph as long as those inactive ingredients meet the applicable regulatory standard for safety and suitability.

94
00:16:52.980 --> 00:17:07.800
Mike Bailey: Similarly, while non-prescription drugs may be produced in compliance with FDA's drug CGMPs, brace determinations do not involve a review of the manufacturing process for each drug marketing under a monograph.

95
00:17:07.970 --> 00:17:18.490
Mike Bailey: Thus, sponsors are not required to submit the level of CMC data to support the OTC GRASE determination that they would be expected to submit under an NDA.

96
00:17:19.010 --> 00:17:27.399
Mike Bailey: We are awaiting FDA Confirmation on this when they finalize the draft guidance on content and format for OMORs under OMUFA I.

97
00:17:28.300 --> 00:17:43.969
Mike Bailey: Finally, GRASE standards when evaluating OMOR submissions for drugs that were previously evaluated by an advisory panel under the

OTC drug review, including, for example, drugs that were classified as category three under a TFM

98
00:17:44.600 --> 00:18:05.170
Mike Bailey: or category one under an ANPR, FDA should not attempt to re-review all of the data the panel already considered. In fact, OMUFA is not resourced to support this. Instead, the statute makes clear that FDA needs to provide the general categories of data that FDA thinks are needed to establish recognition.

99
00:18:05.170 --> 00:18:16.009
Mike Bailey: In other words, FDA should flag gaps that need to be filled and build on previous preliminary findings by the agency and not start a de novo review process.

100
00:18:16.280 --> 00:18:30.980
Mike Bailey: This will allow FDA to uphold rigorous substantive standards while allowing the inefficiencies in either the OMOR process or in the FDA-initiated GRASE determinations on category three ingredient uses

101
00:18:31.870 --> 00:18:33.090
Mike Bailey: Fourth.

102
00:18:33.430 --> 00:18:58.770
Mike Bailey: The industry has agreed to a new investment in quality assurance targeted in a risk-based approach. Unfortunately, a very large number of registered OTC manufacturers have not paid the required user fees. FDA's research shows that this is a predictor for poor quality products. Thus, we support using resources to tackle this situation and improve quality.

103
00:18:59.320 --> 00:19:01.000
Mike Bailey: In conclusion.

104
00:19:01.060 --> 00:19:24.269
Mike Bailey: CHPA and the other three stakeholder groups negotiating OMUFA II have committed to a modest increase in funding for OMUFA II. We are looking forward to moving beyond the establishment of infrastructure for OMUFA and advancing GRASE, finalization, and innovation. Under OMUFA Ii. Such progress is critical

105
00:19:24.460 --> 00:19:27.380
Mike Bailey: ahead of any OMUFA III negotiations.

106
00:19:28.640 --> 00:19:29.435

Mike Bailey: CHPA.

107
00:19:30.570 --> 00:19:36.429
Mike Bailey: We'd like to again thank FDA for organizing this meeting and for giving us the chance to provide these

108
00:19:36.440 --> 00:19:50.189
Mike Bailey: remarks. We look forward to working closely with FDA and other key stakeholders throughout the OMUFA reauthorization process as we work together to ensure the continued success of FDA's OTC

109
00:19:50.390 --> 00:19:52.669
Mike Bailey: review program. Thank you.

110
00:19:54.020 --> 00:19:55.510
Nana Ejiwa Manu: Thank you, Mike.

111
00:19:55.630 --> 00:19:56.630
Nana Ejiwa Manu: Dan,

112
00:19:57.080 --> 00:20:02.440
Nana Ejiwa Manu: you may begin, and I'll make sure to get your camera to the screen so everyone can see you.

113
00:20:05.670 --> 00:20:07.320
Dan Selechnik: Hi! Is everyone able to hear me?

114
00:20:09.000 --> 00:20:10.639
Nana Ejiwa Manu: Yes, we can hear you.

115
00:20:11.120 --> 00:20:12.340
Dan Selechnik: Great. Thank you.

116
00:20:12.900 --> 00:20:19.000
Dan Selechnik: Hi, everyone. My name is Dan Selechnik, and I'm the Director of Regulatory Science with the Fragrance Creators Association.

117
00:20:19.310 --> 00:20:28.039
Dan Selechnik: We at Fragrance Creators first want to thank FDA for putting this meeting together, and for considering the perspectives from stakeholders and regulated industries.

118

00:20:28.340 --> 00:20:36.939
Dan Selechnik: we believe in the work that FDA does, and that industry has a lot of resources and expertise that are valuable to leverage. As FDA forges forward.

119
00:20:37.090 --> 00:20:38.480
Dan Selechnik: Next slide, please.

120
00:20:41.600 --> 00:20:45.530
Dan Selechnik: So, with that being said, I'll 1st give an introduction to Fragrance Creators.

121
00:20:45.550 --> 00:20:50.509
Dan Selechnik: we're the Trade Association, representing the majority of fragrance manufacturing in North America.

122
00:20:50.710 --> 00:20:58.099
Dan Selechnik: Our membership consists of about 60 companies, with everything, from large manufacturers and brands to small family-owned companies.

123
00:20:58.170 --> 00:21:06.599
Dan Selechnik: Our member companies also span the full value chain from suppliers of raw materials to fragrance compounders all the way to finished goods.

124
00:21:07.140 --> 00:21:14.149
Dan Selechnik: Our role as an association is proactively and reactively manage legislative and regulatory matters, among others.

125
00:21:14.170 --> 00:21:22.729
Dan Selechnik: Importantly, a lot of our work is predicated on independent science, done by the Research Institute for Fragrance Materials or RIFM.

126
00:21:23.410 --> 00:21:24.589
Dan Selechnik: Next slide, please.

127
00:21:26.720 --> 00:21:36.209
Dan Selechnik: RIFM is an independent, nonprofit scientific organization that has been dedicated to ensuring that fragrances are used safely since 1966.

128
00:21:36.280 --> 00:21:54.800

Dan Selechnik: They are also member funded with a similar membership to fragrance. Creators of about 60 companies, however, RIFM differs in that they exclusively do science, not advocacy, and because of this, their staff consists of experts in the human health and environmental toxicological endpoints.

129
00:21:55.700 --> 00:21:57.030
Dan Selechnik: Next slide, please.

130
00:22:02.170 --> 00:22:11.419
Dan Selechnik: RIFM's approach to fragrance safety has a few different branches. Their database team maintains a continuously updated database of safety information

131
00:22:12.462 --> 00:22:16.330
Dan Selechnik: continuously updated with the most current literature.

132
00:22:16.560 --> 00:22:27.590
Dan Selechnik: Through industry ingredient usage surveys, RIFM generates exposure data to every fragrance ingredient across product categories, using their Creme-RIFM aggregate exposure model.

133
00:22:28.180 --> 00:22:37.029
Dan Selechnik: Using the tox data in their database and the exposure data that they generate, RIFM conducts detailed risk assessments on every fragrance ingredient

134
00:22:37.140 --> 00:22:39.850
Dan Selechnik: that are peer reviewed and then published.

135
00:22:40.130 --> 00:22:43.180
Dan Selechnik: All these publications are also open access.

136
00:22:43.380 --> 00:22:52.769
Dan Selechnik: In addition, RIFM has a research program dedicated to developing new approach methodologies or NAMs to test fragrance safety without the use of animals.

137
00:22:53.810 --> 00:22:55.150
Dan Selechnik: Next slide, please.

138
00:22:57.840 --> 00:23:10.729
Dan Selechnik: To add another layer of independence, the Expert Panel for Fragrance Safety is another independent team of experts, such as

academics, physicians, and environmental scientists with no affiliation to industry.

139
00:23:10.900 --> 00:23:18.109
Dan Selechnik: They critically review RIFM safety assessments and research projects and have the final say in all safety conclusions.

140
00:23:19.930 --> 00:23:21.150
Dan Selechnik: Next slide, please.

141
00:23:23.690 --> 00:23:36.590
Dan Selechnik: In terms of what studies are used to evaluate fragrance safety. There are a number of guidelines that studies typically adhere to including good laboratory practice or GLP, OECD and NTP.

142
00:23:37.450 --> 00:23:38.680
Dan Selechnik: Next slide, please.

143
00:23:42.540 --> 00:23:46.369
Dan Selechnik: Moving on to the role that fragrances play in OTC drugs.

144
00:23:46.380 --> 00:23:57.749
Dan Selechnik: As excipient ingredients, fragrances are not bioactive, but can have important functions, such as enhancing smell, masking malodor, and generally increasing the appeal to consumers.

145
00:23:59.407 --> 00:24:00.329
Dan Selechnik: Next slide, please.

146
00:24:00.620 --> 00:24:08.530
Dan Selechnik: Because fragrances can be found in OTC drugs, we do appreciate the opportunity to give our input on OMUFA reauthorization.

147
00:24:09.060 --> 00:24:17.530
Dan Selechnik: We want to express our support for OMUFA's goals to promote safety without stifling innovation which deeply aligns with our values as an association.

148
00:24:17.870 --> 00:24:24.400
Dan Selechnik: We also appreciate the flexibility that OMUFA can provide in bringing new and innovative products to market.

149
00:24:24.510 --> 00:24:35.189

Dan Selechnik: Because of this we support the collection of fees for OTC monograph activities but believe in discretion as to where funds are allocated, which I'll elaborate on in the next slide.

150
00:24:37.690 --> 00:24:53.980
Dan Selechnik: To maintain program efficiency, Fragrance Creators suggest that FDA identify industries with a strong safety record and take advantage of existing safety information and expertise. This allows FDA to use their own resources specifically where data gaps exist.

151
00:24:54.570 --> 00:24:55.780
Dan Selechnik: Next slide, please.

152
00:24:58.550 --> 00:25:09.379
Dan Selechnik: We also encourage the FDA Office of Non-Prescription Drugs to share resources with other FDA offices, such as the Office of Cosmetics and Colors, to address any overlap.

153
00:25:09.430 --> 00:25:17.990
Dan Selechnik: Fragrance Creators has been working closely with the Office of Cosmetics and Colors in implementing the modernization of Cosmetics Regulation Act or MoCRA.

154
00:25:18.060 --> 00:25:25.680
Dan Selechnik: and because of this they already have a wealth of information on fragrance safety that can be leveraged in the OMUFA approach as well.

155
00:25:26.360 --> 00:25:27.570
Dan Selechnik: Next slide, please.

156
00:25:28.650 --> 00:25:36.489
Dan Selechnik: So, to summarize Fragrance Creators believes that the OMUFA program can be most efficient if FDA does not have to duplicate work.

157
00:25:36.520 --> 00:25:54.490
Dan Selechnik: We're here to help as the expert source for fragrance related matters and for primarily scientific discourse related to fragrance safety, we do bring in the experts from RIFM, who also have a great amount of data and tools at their disposal that is fully available for FDA as well.

158
00:25:55.210 --> 00:25:56.480
Dan Selechnik: Next slide, please.

159
00:25:57.330 --> 00:26:03.609
Dan Selechnik: thank you so much to FDA again for organizing this meeting and thank you for inviting us to share our thoughts.

160
00:26:07.060 --> 00:26:08.410
Nana Ejiwa Manu: Thank you, Dan.

161
00:26:11.650 --> 00:26:14.530
Nana Ejiwa Manu: Now we will hear from Gil Roth.

162
00:26:14.650 --> 00:26:17.409
Nana Ejiwa Manu: Gil, as our next speaker, you may get started.

163
00:26:23.530 --> 00:26:40.179
Gil Roth: Hi! I'm Gil Roth. I'm the president of the Pharma and Biopharma Outsourcing Association. We're a trade group that represents the CMO and CDMO sector that's primarily in the Rx space, both innovator and generic small and large molecule, but also within the OTC field.

164
00:26:41.640 --> 00:26:55.219
Gil Roth: I'm not going to relitigate the role of facility fees in OMUFA. We disagree with their entire existence. But we're glad that there is a CMO reduction within the structure of OMUFA I and continuing into OMUFA II.

165
00:26:55.640 --> 00:27:14.110
Gil Roth: We're gratified that OMUFA II is going to keep program costs under control as Mike detailed in his presentation. CMOs, who make up a significant portion of the facilities, have narrow margins, even narrower than the OTC Sponsors they work with, and can't absorb large increases in fees going forward.

166
00:27:14.170 --> 00:27:27.040
Gil Roth: We also appreciate that the proposed alignment of OMUFA with the fiscal year does include accommodations for sites to keep them from getting hit with two facility fees in a short period of time.

167
00:27:28.430 --> 00:27:37.764
Gil Roth: The deactivation principle that was brought up also with the office of User Fee collection is also something that we appreciate.

168
00:27:38.630 --> 00:27:54.540

Gil Roth: One of our big issues as negotiations commenced was the disappointment at discovering the sheer amount of facilities that are currently in arrears. A large number of sites numbering in the hundreds have not been paying their OMUFA fees.

169
00:27:54.630 --> 00:28:02.420
Gil Roth: and the assumption is that the calculation of those missing sites is raising fees for the remainder of the sites that are compliant.

170
00:28:02.760 --> 00:28:17.380
Gil Roth: So, we'd like to see greater effort by FDA to collect, and we are glad that there'll be more activity done in OMUFA II providing more information on the arrears sites as well as the compliant sites.

171
00:28:17.380 --> 00:28:33.139
Gil Roth: and on incorporating that status into the FDA's risk-based site selection model, and the agreement that we also had that FDA will provide more information on dunning letters and the efforts they're making towards fee recovery.

172
00:28:33.760 --> 00:28:45.529
Gil Roth: We'd like to see greater effort and enforcement on these noncompliant sites to add more teeth to the program and make sure that the program is fair to the companies that are actually playing by the rules.

173
00:28:45.740 --> 00:29:06.029
Gil Roth: This includes a proposal PBOA made during negotiations that perhaps FDA could cancel or suspend NDCs that are connected to some of these non-paying sites. This would, in all likelihood trigger a financial hit on those companies that would be unable to sell into certain companies that

174
00:29:06.520 --> 00:29:13.809
Gil Roth: keep track of active and inactive NDCs and would potentially spur that fee recovery and collection effort further.

175
00:29:14.320 --> 00:29:24.119
Gil Roth: we understand the need to make this program sustainable. We want to make sure that companies are paying their fair share, and that nobody is being penalized for playing by the rules.

176
00:29:24.240 --> 00:29:32.979
Gil Roth: We look forward to working with the agency and industry going forward in making OMUFA II a success, and I want to thank everybody again for the opportunity to speak today.

177
00:29:34.250 --> 00:29:35.500
Nana Ejiwa Manu: Thank you, Gil

178
00:29:36.120 --> 00:29:39.249
Nana Ejiwa Manu: Emily, as our next speaker. We welcome your comments.

179
00:29:52.290 --> 00:30:18.159
Emily Manoso: Good morning, and thank you, FDA, for hosting this event. My name is Emily Manoso. I'm the Executive Vice President of legal and regulatory affairs at the Personal Care Products Council. I also serve as PCPC, which is our acronym as PCPC's general counsel. I just have a few brief comments this morning. I would like to re-echo a lot of the sentiments already expressed

180
00:30:18.180 --> 00:30:44.220
Emily Manoso: by our other industry regulated industry colleagues. But first, I want to just underscore our appreciation to FDA for hosting this meeting and for all of the work that you have done in collaborating with all stakeholders, including the regulated industries. We appreciate that, and look forward to continued dialogue and collaboration

181
00:30:44.220 --> 00:31:08.390
Emily Manoso: in those respects and are here to serve as a resource in whatever capacity we can. And so, a little background about PCPC. We were founded in 1894. We're a trade association that represents many of the leading brands in the cosmetics and personal care product industry. Our members serve as a unifying voice, and we champion

182
00:31:08.390 --> 00:31:32.159
Emily Manoso: science-based standards and responsible business practices. Our brands are trusted, and they include many of your well-known brands, beloved brands and suppliers, and really the entire value chain our companies manufacture sunscreens, toothpaste, shampoos, moisturizers, and makeup products as well. A few key points

183
00:31:32.160 --> 00:31:46.510
Emily Manoso: from our perspective. One, we are glad to see the continued interaction between FDA and regulated industries, as was articulated in the OMUFA II commitment letter.

184
00:31:46.520 --> 00:32:10.700
Emily Manoso: We also appreciate the proposed update to the definition of in-person meetings to include the virtual options and the alignment with that proposal for other user fee programs. We would echo the sentiments

expressed by our colleagues at CHPA that OTC reform through the Cares Act did not

185
00:32:10.700 --> 00:32:25.490
Emily Manoso: change the generally recognized safe and effective or GRASE Standard, and we would urge FDA to, you know, maintain the principles long articulated on how the GRASE standard should be approached.

186
00:32:25.530 --> 00:32:31.769
Emily Manoso: Lastly, we're also keen on the proposed addition of the tier two

187
00:32:31.970 --> 00:32:52.850
Emily Manoso: or OMOR regarding the test methods, and we look forward to learning about that in particular, more detail and the opportunity to comment as proposed, and in summary we just look forward to continuing to represent the interests of our members and look forward to providing further comments as requested. Thank you.

188
00:32:53.730 --> 00:32:58.450
Nana Ejiwa Manu: Thank you, Emily. James, as our next speaker, you may begin.

189
00:33:04.410 --> 00:33:08.089
James Kim: Okay, good morning, everyone. Thank you for having us today.

190
00:33:08.160 --> 00:33:16.319
James Kim: My name is Jim Kim, and I am the senior Vice President of Science and Regulatory Affairs at the American Cleaning Institute or ACI.

191
00:33:16.490 --> 00:33:25.130
James Kim: We appreciate the opportunity to share our perspective and provide recommendations as part of the OMUFA II reauthorization process.

192
00:33:26.130 --> 00:33:33.250
James Kim: ACI is a trade association that serves the growth and innovation of the United States cleaning products industry.

193
00:33:33.700 --> 00:33:48.470
James Kim: In addition to formulators and suppliers of soaps, detergents, and general cleaning products, our members also include manufacturers and suppliers of consumer and healthcare, topical antiseptic over-the-counter drug products sold in the Us.

194

00:33:49.260 --> 00:33:59.240
James Kim: This includes manufacturers and suppliers of topical antiseptic ingredients deferred by FDA from final rulemaking under the OTC drug review process.

195
00:34:00.120 --> 00:34:12.969
James Kim: ACI is leading a multi-year multimillion dollar effort to complete the FDA requested studies for the topical antiseptic ingredients, Ethanol, Benzylconium Chloride, and Chlorozylenol,

196
00:34:12.989 --> 00:34:17.959
James Kim: to establish the general recognition of safety and effectiveness status.

197
00:34:19.500 --> 00:34:25.080
James Kim: We are the only industry coalition addressing these topical, antiseptic, active ingredients

198
00:34:26.219 --> 00:34:32.529
James Kim: as noted earlier under the Coronavirus Aid Relief and Economic Securities Act or the Cares Act.

199
00:34:32.730 --> 00:34:41.370
James Kim: the deferred antiseptic ingredients are considered lawfully marketed. Although FDA has not yet made a final GRASE determination.

200
00:34:41.530 --> 00:34:45.380
James Kim: and we urge FDA to consider, and allocate resources

201
00:34:45.389 --> 00:34:52.840
James Kim: to support solutions, to address some of the challenges that we are experiencing in the GRASE finalization process.

202
00:34:52.900 --> 00:34:57.330
James Kim: And our comments highlight areas where additional support from FDA

203
00:34:57.390 --> 00:35:04.070
James Kim: during the OMUFA II cycle will be important to the success of our ongoing topical antiseptic programs.

204
00:35:05.630 --> 00:35:06.650
James Kim: First,

205
00:35:06.890 --> 00:35:14.190
James Kim: transparent, timely, and robust scientific interactions with FDA on our topical antiseptic programs are crucial.

206
00:35:14.460 --> 00:35:21.779
James Kim: FDA has requested significant amounts of data based on numerous studies to support GRASE finalization.

207
00:35:22.210 --> 00:35:31.860
James Kim: We have submitted multiple reports to FDA, demonstrating our ongoing progress in generating safety and effectiveness data to satisfy FDA's requirements.

208
00:35:31.980 --> 00:35:40.739
James Kim: And we have also met with FDA through formal meetings to discuss our study designs and data and will continue to do so, as appropriate.

209
00:35:41.140 --> 00:35:46.280
James Kim: However, we'd like FDA to help support our data development programs in two ways.

210
00:35:46.850 --> 00:35:54.249
James Kim: We ask that FDA provide clearer, more definitive guidance on its thinking about whether our studies and data

211
00:35:54.280 --> 00:36:02.730
James Kim: appear acceptable to support a GRASE determination, instead of telling us that an issue will be, “a matter of review.”

212
00:36:03.490 --> 00:36:14.759
James Kim: Without clear direction from FDA as we proceed, there is a risk that we will, after significant time, energy, and expense, ultimately not meet FDA's expectations.

213
00:36:15.910 --> 00:36:23.099
James Kim: Ideally, we're trying to prevent such a disconnect, and instead have more definitive agreement up front from the agency.

214
00:36:24.000 --> 00:36:35.420
James Kim: For example, some assurances at interim time points that are completed pilot studies were designed and executed in a manner likely to satisfy the GRASE standards are needed

215
00:36:35.670 --> 00:36:41.700
James Kim: before we can initiate our pivotal clinical studies, which are highly costly and time consuming.

216
00:36:41.900 --> 00:36:54.889
James Kim: We are looking for feedback that is analogous to when FDA advises an NDA product sponsor that one of its studies or its development program more generally appear acceptable to support product approval.

217
00:36:55.290 --> 00:37:02.570
James Kim: ACI would welcome scientific dialogue and FDA's feedback on the sufficiency of our data at each step of the process.

218
00:37:02.630 --> 00:37:07.080
James Kim: With an understanding that the GRASE determination in the final order

219
00:37:07.300 --> 00:37:11.149
James Kim: will be based on the weight of all available evidence at that time.

220
00:37:11.690 --> 00:37:16.860
James Kim: We believe that such transparency is also in the public interest

221
00:37:16.950 --> 00:37:20.290
James Kim: because it gives us time to fill any additional data gaps

222
00:37:20.330 --> 00:37:25.150
James Kim: rather than risking an unfavorable GRASE determination due to a disconnect.

223
00:37:26.260 --> 00:37:33.160
James Kim: Next, we also ask that FDA provide this interim ongoing feedback via more informal mechanisms.

224
00:37:33.450 --> 00:37:43.759
James Kim: We'd appreciate the ability to have back and forth communications with FDA as needed to obtain the agency's thinking without having to go through the formal meeting processes.

225
00:37:44.350 --> 00:37:56.579

James Kim: For example, we would appreciate comments on a protocol, proposed study design, or overall development plans with a review by FDA and the provision of feedback in real time to expedite the process,

226
00:37:56.750 --> 00:37:59.519
James Kim: add clarity, and provide needed direction.

227
00:38:00.390 --> 00:38:06.119
James Kim: And perhaps this can take the form of feedback letters, email comments, or something similar along those lines.

228
00:38:07.660 --> 00:38:16.629
James Kim: Additionally, we note for the agency that these studies are highly costly and time consuming, and while ACI is committed to funding robust and rigorous studies.

229
00:38:16.800 --> 00:38:22.049
James Kim: Fulfilling this commitment requires us to use our limited resources efficiently.

230
00:38:22.910 --> 00:38:33.929
James Kim: In our experience with topical antiseptics there have been and will continue to be disagreements between us and FDA on issues of study design and data interpretation.

231
00:38:34.080 --> 00:38:36.550
James Kim: And while many issues can be resolved,

232
00:38:36.740 --> 00:38:44.660
James Kim: if the parties cannot agree on a reasonable path forward, there is currently no real mechanism to resolve scientific disputes.

233
00:38:45.390 --> 00:38:49.840
James Kim: The formal dispute resolution guidance only applies to final orders.

234
00:38:50.410 --> 00:38:57.979
James Kim: So, we would ask that FDA outline a pathway for resolving scientific disputes that occur at the data generation stage.

235
00:38:59.040 --> 00:39:17.399
James Kim: An efficient, informal dispute resolution process is necessary for manufacturers and other stakeholders like ACI to resolve important

questions about clinical trial design, including disputes around success criteria, and to continue making progress towards GRASE finalization.

236
00:39:18.030 --> 00:39:31.219
James Kim: And to conclude ACI appreciates FDA's efforts to collaborate with our organization on finalizing GRASE determinations and the agency's work during OMUFA I to set up the infrastructure under monograph reform.

237
00:39:31.970 --> 00:39:44.020
James Kim: During OMUFA II, we hope to see FDA support industries' efforts to generate the safety and efficacy data for the lawfully marketed products requested by FDA and to make a GRASE determination.

238
00:39:44.230 --> 00:39:51.680
James Kim: And thank you very much for your time today, and I appreciate the opportunity to have been a part of the OMUFA II negotiation team. Thank you.

239
00:39:52.390 --> 00:39:53.550
Nana Ejiwa Manu: Thank you, Jim.

240
00:39:54.050 --> 00:39:57.570
Nana Ejiwa Manu: Now, Meredith, as our last speaker, please begin.

241
00:40:03.800 --> 00:40:05.080
Meredith Petillo: Good morning.

242
00:40:05.490 --> 00:40:14.360
Meredith Petillo: Thank you. Dr. Michelle and the FDA Team for putting this meeting together and for the opportunity to speak today on this industry representation panel. My name is Meredith Petillo.

243
00:40:14.430 --> 00:40:31.260
Meredith Petillo: and I'm the Vice President of Technical and Regulatory Affairs at the Independent Beauty Association, a nonprofit Trade association. Since 1974 IBA has been the voice of small and independent cosmetics companies now representing over 600 organizations in the Indie beauty and personal care industry.

244
00:40:31.350 --> 00:40:48.810
Meredith Petillo: The IBA membership includes monograph OTC drug manufacturing facilities, brands who are using these contract manufacturers to produce OTC personal care products on their behalf, as well as stakeholders from the rest of the supply chain, including testing

labs, raw material and packaging suppliers, regulatory consultants, law firms, and more.

245
00:40:48.920 --> 00:40:57.879
Meredith Petillo: I'm here today to speak specifically on behalf of small to medium sized businesses who are stakeholders in the overlap between monograph OTC drugs and cosmetics.

246
00:40:57.960 --> 00:41:17.500
Meredith Petillo: This overlap between these two regulated product categories is essential to not only understanding the relevance of businesses in the beauty sector to today's OMUFA meeting, but also in assessing the impact of OMUFA reauthorization may have on IBA member companies, other small entrepreneurial businesses, and ultimately the product choice available to US Consumers.

247
00:41:18.500 --> 00:41:30.790
Meredith Petillo: Speaking briefly on product categories, certain topical, over-the-counter drug products sit at the interface of monograph OTC and cosmetic classification. And these products play an important role in the US Consumer hygiene and personal care routine.

248
00:41:30.900 --> 00:41:40.609
Meredith Petillo: The following product categories are examples that sit at this nexus, sunscreens, anti-acne anti-dandruff, skin protectants, topical analgesics, and antiperspirants.

249
00:41:41.320 --> 00:41:45.580
Meredith Petillo: These are not products that are used infrequently for occasional treatment or an intermittent need.

250
00:41:45.990 --> 00:41:56.600
Meredith Petillo: OMUFA plays an important role in FDA's ability to maintain a selection of safe, effective, useful, pleasant, innovative, and affordable products that are suitable for all skin and hair types.

251
00:41:56.920 --> 00:41:59.869
Meredith Petillo: This product choice is important to the US Consumer.

252
00:41:59.960 --> 00:42:05.349
Meredith Petillo: It is critical that FDA has adequate resourcing to accomplish this goal on behalf of the US Consumer.

253
00:42:05.800 --> 00:42:13.000

Meredith Petillo: IBA appreciates the public comment and crowdsourcing opportunities for stakeholder participation in the OMOR process.

254
00:42:13.160 --> 00:42:26.029
Meredith Petillo: The submission of an OMOR is financially out of scope for many small businesses in the IBA membership. So, the opportunity to provide public comment input at various touch points that the proposed recommendations outline will be important for stakeholders to track.

255
00:42:26.590 --> 00:42:37.530
Meredith Petillo: The education offerings outlined in the commitment letter in service of enhancing quality surveillance are also well appreciated by small business, such as the CGMP Workshop slated by the end of fiscal year 2028.

256
00:42:37.540 --> 00:42:41.800
Meredith Petillo: IBA encourages FDA to continue, if resourcing permits,

257
00:42:41.880 --> 00:42:51.499
Meredith Petillo: to expand offerings of critical industry, education to help ensure businesses of all sizes, especially new entrants to the OTC monograph manufacturing space are well versed

258
00:42:51.750 --> 00:42:54.849
Meredith Petillo: in the coming years on how to meet quality obligations.

259
00:42:55.050 --> 00:43:03.409
Meredith Petillo: In addition to the specifics of the commitment letter at hand, there are overarching, small business related OMUFA observations member companies have relayed to IBA.

260
00:43:03.610 --> 00:43:12.569
Meredith Petillo: Due to the high investment of self manufacture, many small to medium sized brands, selling these specific monograph drug products use contract manufacturers to produce their products.

261
00:43:12.750 --> 00:43:17.450
Meredith Petillo: Vertical or in-house manufacturing is not common in the indie beauty and personal care space.

262
00:43:17.640 --> 00:43:25.730
Meredith Petillo: Many of the contract manufacturers that produce the topical monograph OTCs are cosmetic product manufacturers who also manufacture OTC products.

263
00:43:26.010 --> 00:43:37.279
Meredith Petillo: Given the higher investment required to produce and maintain OTC products in market, OTC formulas are typically a much smaller percentage of those contract manufacturers' product portfolio compared to cosmetics.

264
00:43:37.600 --> 00:43:46.789
Meredith Petillo: OTC product manufacturing requires appropriate equipment, systems, and highly trained personnel to meet quality and regulatory compliance mandates throughout the development and manufacturing process.

265
00:43:47.090 --> 00:43:50.660
Meredith Petillo: On top of this, are fee requirements for OTC production

266
00:43:50.830 --> 00:43:57.329
Meredith Petillo: facilities that are not adjusted for the size of the business or the size of the OTC manufacturing portfolio within the facility.

267
00:43:57.550 --> 00:44:09.719
Meredith Petillo: Furthermore, small startup brands often require low production quantities to launch their product lines. It is challenging to identify contract manufacturers who can provide small order quantities necessary to support an emerging cosmetics business.

268
00:44:09.810 --> 00:44:24.639
Meredith Petillo: We're talking about production runs counted in hundreds or thousands versus hundreds of thousands or millions of units. So, economies of scale don't benefit small producers. The scarcity is compounded further when looking for manufacturers who can produce OTC products at low minimum order quantities.

269
00:44:25.270 --> 00:44:45.580
Meredith Petillo: IBA member companies are concerned with maintaining a healthy number of compliant, responsible, and viable monograph OTC Contract manufacturers who can accommodate business of a wide variety of sizes and scale. OMUFA facility fees can affect a business's choice to enter or exit the OTC manufacturing space. Specifically in the topical monograph, OTC Cosmetic space.

270
00:44:46.270 --> 00:44:58.790
Meredith Petillo: The facility fee may not be the only deciding factor, of course, but IBA continues to hear from member companies that it is a consideration businesses will be evaluating when thinking about entering the OTC manufacturing space in our sector of products.

271
00:44:59.230 --> 00:45:04.760
Meredith Petillo: And new innovative products may never make it to shelf if more manufacturers choose to exit the OTC business.

272
00:45:05.870 --> 00:45:13.460
Meredith Petillo: Following OMUFA implementation, some contract manufacturers have exited OTC business following the initial fiscal years of facility fees.

273
00:45:13.610 --> 00:45:27.750
Meredith Petillo: Continued reduction in the number of OTC-qualified contract manufacturers, especially facilities who accommodate low minimum order quantity production runs, should be monitored as it could lead to further reduced topical monograph OTC product choice for the consumer.

274
00:45:27.880 --> 00:45:36.040
Meredith Petillo: Reduced availability and higher demand for production facilities lead to typical cost-based competition for scarce manufacturing resources.

275
00:45:36.080 --> 00:45:43.209
Meredith Petillo: A significant reduction in the number of OTC product manufacturers in the future could create supply bottlenecks and reduce redundancy.

276
00:45:43.310 --> 00:45:59.609
Meredith Petillo: Small entrepreneurial brands may not be able to find manufacturers or may be locked out of production if larger customers take precedence in production schedule, effectively reducing the variety of new products that offer innovation or serve smaller markets, diverse skin and hair types, or niche consumer needs.

277
00:45:59.960 --> 00:46:08.360
Meredith Petillo: Additionally, it is important to note that the OMOR tier one and tier two fees are financially out of reach for small personal care businesses, whether they are brands or manufacturers.

278
00:46:08.770 --> 00:46:14.559
Meredith Petillo: For context, IBA is a small nonprofit association and about half of our 600 Member Organizations

279
00:46:14.720 --> 00:46:21.799
Meredith Petillo: report revenue of less than 1 million dollars per year. A tier one OMOR request is unfortunately simply fiscally unattainable.

280
00:46:22.430 --> 00:46:30.099
Meredith Petillo: The IBA appreciates the touch points for public comment and engagement outlined in the commitment letter, and FDA's continued commitment to industry education.

281
00:46:30.110 --> 00:46:39.869
Meredith Petillo: IBA respectfully requests that FDA continues to consider and incorporate small business concerns in the reauthorization process for the OMUFA program, wherever possible.

282
00:46:39.970 --> 00:46:48.669
Meredith Petillo: Small business considerations should be in place to protect against further significant business exit from OTC manufacturing and to assist with fair and equitable access

283
00:46:48.710 --> 00:46:52.769
Meredith Petillo: for the entry of new small business manufacturers into this space.

284
00:46:53.140 --> 00:47:06.009
Meredith Petillo: Thank you all for your time. Today IBA remains a resource for FDA at any time, for insights and information regarding OMUFA impact specifically for small to medium sized businesses in the overlap space between cosmetics and monograph drugs.

285
00:47:06.340 --> 00:47:07.250
Nana Ejiwa Manu: Thank you.

286
00:47:08.490 --> 00:47:13.830
Nana Ejiwa Manu: Thank you, Meredith, that concludes our session on regulated industry perspectives.

287
00:47:15.960 --> 00:47:30.389
Nana Ejiwa Manu: Our final session will be on academic and advocacy perspectives. We will hear from Dr. Eric Brass, who is from the University of California, Los Angeles and Dr. Diana Zuckerman, who is from the National Center for Health Research.

288
00:47:30.540 --> 00:47:32.990
Nana Ejiwa Manu: Dr. Brass. We welcome your comments.

289
00:47:43.250 --> 00:47:55.409

Eric Brass: Good morning and thank you. I appreciate the opportunity to share my perspective on the opportunities and challenges offered by OMUFA specifically as relates to improving the public health.

290
00:47:56.660 --> 00:48:05.429
Eric Brass: As this audience knows, the OTC monograph has facilitated consumer access to safe and effective ingredients in a broad range of drug products for 50 years.

291
00:48:05.620 --> 00:48:12.849
Eric Brass: However, the monograph process was born out of necessity and has often limited important actions by both industry and regulators.

292
00:48:13.820 --> 00:48:17.360
Eric Brass: OMUFA I initiated long overdue reforms.

293
00:48:18.120 --> 00:48:31.460
Eric Brass: FDA's work today, as you've heard, is focused on developing the infrastructure and tools needed to institute those reforms, but we now have the opportunity to apply them specifically on opportunities related to improving public health.

294
00:48:32.880 --> 00:48:45.969
Eric Brass: That's in part reflected in some of the FDA's latest forecast for planned monograph activities. But it's really leveraging these opportunities to improve public health where the largest opportunities, I think, lie.

295
00:48:47.310 --> 00:48:53.700
Eric Brass: As you've heard, a key tool in implementing these reforms is the over-the-counter monograph order request, or OMOR.

296
00:48:53.900 --> 00:49:04.580
Eric Brass: And without going into great detail, I want to highlight two specific types of OMORs that were in the proposed commitment letter, because they're relevant to two examples I'd like to share with you.

297
00:49:04.590 --> 00:49:15.590
Eric Brass: The first, as you've heard about is the addition of a new ingredient to a monograph that already has one or more ingredients that have been found to be generalized, recognized, safe and effective.

298
00:49:15.660 --> 00:49:25.459

Eric Brass: And the second is the specified safety change OMOR, where an instruction about dosage and administration that is intended to increase the safe use of the monograph drug product.

299
00:49:26.170 --> 00:49:33.300
Eric Brass: That's particularly of interest because it has a shorter timeline for FDA action and can be used in a more facile way.

300
00:49:33.860 --> 00:49:49.189
Eric Brass: Now, I'd like to share two examples with you, not because I think they are necessarily the most important examples, but I think they're relevant to illustrate what I think, are going to be challenges in leveraging the opportunities to improve public health.

301
00:49:50.600 --> 00:49:55.220
Eric Brass: The first has to do with medication errors with pediatric acetaminophen products.

302
00:49:55.460 --> 00:50:03.730
Eric Brass: Pediatric acetaminophen is an important product that helps treat millions of children, particularly its use as an antipyretic.

303
00:50:04.040 --> 00:50:08.449
Eric Brass: Nonetheless, while it is safe when used as directed

304
00:50:08.480 --> 00:50:23.199
Eric Brass: medication errors do occur, and recognizing this, the industry took steps voluntarily to mitigate these in 2011, which included but were not limited to tabular format for dosing, including both weight and age-based dosing.

305
00:50:23.270 --> 00:50:25.490
Eric Brass: The use of milliliter units

306
00:50:25.680 --> 00:50:30.169
Eric Brass: the inclusion of a calibrated dosing device consistent with the dosing instructions.

307
00:50:30.220 --> 00:50:43.380
Eric Brass: and to standardize the concentration of liquid products at 160 mils per 5 mLs. Many of these were then later incorporated into guidances that the FDA issued, but of course the monograph was the monograph for Acetaminophen.

308

00:50:44.370 --> 00:50:49.969
Eric Brass: To look at the impact of these changes, we had access to data from the national poison data system

309
00:50:50.120 --> 00:50:53.679
Eric Brass: to look at what happened after implementation of those changes.

310
00:50:54.310 --> 00:51:02.649
Eric Brass: And if you look at the figure, if you look at the solid line after 2011, when the changes were introduced

311
00:51:02.660 --> 00:51:10.360
Eric Brass: there was a marked decrease in exposures that were attributable to medication errors reported to the national data system.

312
00:51:10.490 --> 00:51:25.070
Eric Brass: This was temporarily associated with the implementation of voluntary changes as illustrated by the standardization of the 160 milligram, the increased sales of the 160 milligram per 5 mL product in the dotted line.

313
00:51:26.310 --> 00:51:33.940
Eric Brass: While this decrease was encouraging, there were still a large number of residual errors that were being observed.

314
00:51:34.410 --> 00:51:37.509
Eric Brass: And when we look at those residual errors.

315
00:51:37.830 --> 00:51:44.620
Eric Brass: The striking finding is that 66% of them occurred in children under the age of two.

316
00:51:44.800 --> 00:51:48.309
Eric Brass: When the caregivers were asked where they got their dosing instructions

317
00:51:48.470 --> 00:51:50.809
Eric Brass: 21% said from the packaging

318
00:51:50.990 --> 00:51:57.849
Eric Brass: 9% from prior experience, 3% from friends and relatives, and 69% said from health professionals.

319
00:51:58.410 --> 00:52:04.449
Eric Brass: The challenge, of course, is that the label dosing instruction for children under two says simply, “Ask a doctor.”

320
00:52:05.020 --> 00:52:18.639
Eric Brass: So those individuals who were taking information from the label were clearly getting misinformation. Those who were getting information from other sources, had no reference point on the label to make sure they were dosing the product

321
00:52:19.160 --> 00:52:20.150
Eric Brass: correctly.

322
00:52:21.530 --> 00:52:27.000
Eric Brass: Clearly, consumers need more information to dose these children properly.

323
00:52:27.540 --> 00:52:46.489
Eric Brass: Now, I'm pleased to see that the FDA's plan activities include addressing dosing strengths of oral single ingredient pediatric acetaminophen products. It includes proposing the addition of weight and age-based dosing for children under 12, which reflects largely the voluntary actions that have been in place for almost 15 years now.

324
00:52:46.710 --> 00:52:53.339
Eric Brass: What's not clear is whether it includes adding dosing information for children under the age of two.

325
00:52:53.660 --> 00:53:05.709
Eric Brass: I would suggest that such an addition actually meets the criteria for a specified safety change in the shorter review timelines because it's clearly a documented, evidence-based public health need.

326
00:53:07.570 --> 00:53:12.639
Eric Brass: The next example. I'd like to briefly share with you has to do with adding new ingredients to the monograph.

327
00:53:13.570 --> 00:53:20.409
Eric Brass: The existing monograph for antihistamine active ingredients includes diphenhydramine, chlorpheniramine and a number of other products.

328
00:53:20.810 --> 00:53:29.199

Eric Brass: but since that time the second generation, antihistamines have entered OTC marketing and include loratadine, fexofenadine, cetirizine, and others.

329
00:53:29.430 --> 00:53:37.700
Eric Brass: Which raises the question, should the second-generation antihistamines be added to the monograph? And you'll see from here on

330
00:53:37.850 --> 00:53:40.679
Eric Brass: my discussion is going to be full of question marks

331
00:53:40.990 --> 00:53:53.050
Eric Brass: because that's exactly what I'm trying to understand. Now, the answers to many of these questions may be clear to many in the room, but they're certainly not clear to me, and I would suggest that more transparent answers to many of them would be helpful.

332
00:53:53.260 --> 00:53:59.389
Eric Brass: Now, adding the second-generation antihistamines to the monograph might have a number of potential advantages.

333
00:53:59.580 --> 00:54:04.210
Eric Brass: It may provide more opportunities for innovation by the industry,

334
00:54:04.290 --> 00:54:06.480
Eric Brass: generating new OTC products.

335
00:54:06.810 --> 00:54:10.840
Eric Brass: It may allow for more consistent reporting requirements for industry.

336
00:54:10.890 --> 00:54:20.569
Eric Brass: And it may result in more facile review and action by the FDA. But whether those potential advantages can actually occur

337
00:54:20.930 --> 00:54:23.079
Eric Brass: remains unclear to me.

338
00:54:24.100 --> 00:54:31.870
Eric Brass: And that sets up a number of additional challenges and questions from my perspective in trying to use these mechanisms to improve public health.

339
00:54:32.670 --> 00:54:38.290
Eric Brass: For example, who has the incentive to initiate an OMOR under these procedures.

340
00:54:38.910 --> 00:54:43.759
Eric Brass: Clearly the FDA does, and importantly, when they need to address a safety concern.

341
00:54:44.880 --> 00:54:59.829
Eric Brass: Now, I just emphasize, as I have in other forms in the past, that such assessment, even if triggered by a safety concern, should include a transparent assessment of both benefit and risk in the decision making, because the benefits may still

342
00:54:59.960 --> 00:55:06.790
Eric Brass: outweigh any new risks that are identified, so that assessment needs to be explicit and transparent.

343
00:55:08.100 --> 00:55:17.309
Eric Brass: But from the industry's perspective, what's the potential advantage for adding a new ingredient to the monograph versus using the NDA process?

344
00:55:17.800 --> 00:55:29.350
Eric Brass: If it's an existing ingredient, such as the second-generation antihistamines, all manufacturers will benefit, while potentially only one manufacturer incurs the cost of filing the order.

345
00:55:29.900 --> 00:55:47.659
Eric Brass: While there's the potential for exclusivity, it's unclear how that could be applied to an existing ingredient, as both of my examples include, because multiple manufacturers are already using that ingredient in marketed products. So how could exclusivity be established?

346
00:55:49.090 --> 00:55:54.240
Eric Brass: Who has the incentive to generate and submit data to support an OMOR under these procedures?

347
00:55:54.460 --> 00:55:57.169
Eric Brass: Consider the Acetaminophen dosing question.

348
00:55:57.180 --> 00:55:59.150
Eric Brass: A clear public health need.

349
00:55:59.610 --> 00:56:10.930
Eric Brass: One might expect before one puts such dosing information on the label, access to pharmacokinetic data in the under-2 age group, a comprehensive review of safety data,

350
00:56:10.990 --> 00:56:15.130
Eric Brass: understanding of pharmacodynamic relationships for the product in that age group.

351
00:56:15.450 --> 00:56:27.080
Eric Brass: Who has that data? And does the holder of the data have any incentive to initiate the process or even participate in a process that's initiated by the agency? Nana Adjeiwaa-Manu: Dr. Brass, you have about a minute left.

352
00:56:29.070 --> 00:56:34.070
Eric Brass: I'd also ask whether the filing requirements for an OMOR are too inflexible or onerous?

353
00:56:34.420 --> 00:56:42.020
Eric Brass: Should there be more flexibility in the ability to tailor the content of the OMOR to meet the needs of the submission requirement?

354
00:56:42.260 --> 00:57:00.479
Eric Brass: Consider the second-generation antihistamines. It's obvious that they meet the standards of generalized, recognized, safe, and effective (GRASE, labeling already exists, why would one need more than a simple summary of the status and rationale to petition for a switch if that was in anybody's interest to so do?

355
00:57:01.250 --> 00:57:14.670
Eric Brass: OMOR submissions would also obviously be facilitated by early explicit agreement between the FDA and sponsor on those data requirements, as you've heard from previous speakers.

356
00:57:15.740 --> 00:57:17.150
Eric Brass: So in summary,

357
00:57:18.036 --> 00:57:19.270
Eric Brass: excuse me,

358
00:57:19.710 --> 00:57:28.459
Eric Brass: OMUFA and the OMOR processes provide mechanisms that can be used for improving consumer access to safe and effective OTC drugs.

359
00:57:29.330 --> 00:57:36.719
Eric Brass: The addition of currently marketed OTC drugs to existing monograph categories may help rationalize the regulatory structure.

360
00:57:37.350 --> 00:57:47.530
Eric Brass: Acetaminophen dosing for children under 2 is an example where a specified safety change has the potential to immediately impact the public health by reducing medication errors.

361
00:57:48.190 --> 00:57:56.469
Eric Brass: However, it's unclear to me if incentives exist for industry to utilize these mechanisms in the context that I've discussed.

362
00:57:56.730 --> 00:57:58.660
Eric Brass: I thank you very much for your attention.

363
00:57:59.580 --> 00:58:01.330
Nana Adjeiwaa-Manu: Thank you, Dr. Brass.

364
00:58:01.380 --> 00:58:04.039
Nana Adjeiwaa-Manu: Dr. Zuckerman, you may now begin.

365
00:58:14.590 --> 00:58:30.149
Diana Zuckerman: Thank you very much. I'm Dr. Diana Zuckerman, President of the National Center for Health Research. We're a nonprofit public health think tank, and we don't accept funding from any entities that have a financial interest in the work that we do.

366
00:58:32.220 --> 00:58:48.330
Diana Zuckerman: Thank you very much for the opportunity to share our views today. I should also mention that we're a member of the patient Consumer and Public Health Coalition, so we work very closely, with a variety of nonprofit consumer, patient, and medical professional groups.

367
00:58:49.710 --> 00:59:06.999
Diana Zuckerman: Prior to my current position, I was a postdoc in epidemiology and public health at Yale, and a researcher PI and faculty member at Yale and Harvard, and then I moved to Washington, DC and worked in the House of Representatives, the U.S. Senate, and the White House,

368
00:59:07.250 --> 00:59:22.219

Diana Zuckerman: working on a variety of FDA issues. And I'm also a founding board member of the Alliance for a Stronger FDA, which educates Congress about the importance of giving funding appropriations

369
00:59:22.300 --> 00:59:23.880
Diana Zuckerman: to the FDA.

370
00:59:25.160 --> 00:59:28.349
Diana Zuckerman: Our Center has strongly supported

371
00:59:29.265 --> 00:59:30.130
Diana Zuckerman: OMUFA

372
00:59:30.370 --> 00:59:48.580
Diana Zuckerman: and the monograph reforms, and I also want to thank Dr. Brass. I agree with everything you said, and I don't say that very often, and I also agree with almost everything said by the previous panel, so we're starting from that good place. However,

373
00:59:49.210 --> 00:59:51.560
Diana Zuckerman: we have had concerns that

374
00:59:52.180 --> 00:59:54.010
Diana Zuckerman: when OMUFA

375
00:59:54.070 --> 01:00:02.920
Diana Zuckerman: was based on PDUFA, and although PDUFA has had a lot of benefits in a variety of ways,

376
01:00:02.930 --> 01:00:19.499
Diana Zuckerman: it does not really focus on patients and consumers as much as we think it should, and OMUFA, of course, should focus on it more, since these are consumer products that millions and millions of people are using every day.

377
01:00:20.640 --> 01:00:24.910
Diana Zuckerman: So, in previous meetings

378
01:00:25.600 --> 01:00:38.740
Diana Zuckerman: on this topic, we have found that the consumers are very concerned about GRASE standards. We all agree that they should be scientifically based,

379

01:00:38.950 --> 01:00:46.630
Diana Zuckerman: but especially with new information coming out about endocrine disrupting chemicals, whether they're phthalates,

380
01:00:46.920 --> 01:01:05.429
Diana Zuckerman: or PFAS chemicals, or other endocrine disrupting chemicals, that these are examples of things that have been assumed to be safe, and we're finding out more and more that they're not safe, but we don't have very good tests for a lot of these chemicals, so we can't really say very much about

381
01:01:05.500 --> 01:01:08.250
Diana Zuckerman: how safe they are or aren't.

382
01:01:10.240 --> 01:01:16.970
Diana Zuckerman: We've also expressed concerns, as have other nonprofit groups, about combination medical products.

383
01:01:17.380 --> 01:01:36.779
Diana Zuckerman: For example, once cold medications that contain Acetaminophen, but also contain other ingredients, and then patients don't understand that. And so, they take cold medications, and they take acetaminophen or take various cold medication products at the same time and end up in the ER.

384
01:01:37.920 --> 01:01:44.509
Diana Zuckerman: So, I just want to talk about 2 ways that we hope that OMUFA will be

385
01:01:44.790 --> 01:01:51.349
Diana Zuckerman: superior to PDUFA and MDUFA, for that matter. But I know that your main focus has been PDUFA.

386
01:01:51.390 --> 01:02:05.519
Diana Zuckerman: So, one way is that performance goals have focused too much on speed and getting reviews done quickly, and not enough on safety and effectiveness, which is what consumers really care about.

387
01:02:06.010 --> 01:02:19.339
Diana Zuckerman: And, secondly, that the negotiations between industry and the FDA have been behind closed doors in PDUFA, with very little meaningful input

388
01:02:19.420 --> 01:02:24.369

Diana Zuckerman: from the public health community, from consumers and from patient groups.

389
01:02:25.860 --> 01:02:54.699
Diana Zuckerman: So, I'm going to address the second one first, the negotiations, because that's the simple one. The negotiations have been behind closed doors. There were only 2 meetings with consumer groups. They were very early in the process, and then the minutes of the meetings are available, but they're skimpy. They don't include very much information that's very useful for understanding what happened.

390
01:02:55.130 --> 01:02:57.530
Diana Zuckerman: I've looked at the minutes,

391
01:02:57.620 --> 01:03:03.850
Diana Zuckerman: very fun. In almost every case where there was a proposal or a disagreement

392
01:03:04.030 --> 01:03:08.150
Diana Zuckerman: from either FDA or industry, there was

393
01:03:08.240 --> 01:03:14.640
Diana Zuckerman: pretty much no useful information about the content of those proposals,

394
01:03:14.850 --> 01:03:17.430
Diana Zuckerman: the content of the disagreement

395
01:03:17.500 --> 01:03:20.190
Diana Zuckerman: in the minutes, and as a result,

396
01:03:20.550 --> 01:03:29.990
Diana Zuckerman: we weren't really able to understand what was happening in these negotiations. And that's also typical of PDUFA and MDUFA, and it’s

397
01:03:30.070 --> 01:03:34.109
Diana Zuckerman: one of the ways that we hope OMUFA will be different.

398
01:03:34.840 --> 01:03:57.989
Diana Zuckerman: To go back to the main issue, which is safety and effectiveness, which are the most important things to consumers, of course, and to the nonprofit community, and we can't help but think that if we were part of the process of these negotiations, there would be more

metrics pertaining to safety and effectiveness in the commitment letter than there are today.

399
01:03:59.570 --> 01:04:08.640
Diana Zuckerman: However, there are some mentions in the minutes that are relevant to consumer confidence and quality issues. So, I want to take a few minutes to talk about those.

400
01:04:11.250 --> 01:04:16.000
Diana Zuckerman: We noted in the minutes that when the FDA tried to include

401
01:04:16.190 --> 01:04:23.940
Diana Zuckerman: ways to focus on quality at these meetings, there was pushback, and that industry came back

402
01:04:24.130 --> 01:04:29.160
Diana Zuckerman: with a counterproposal that would reduce the FTEs

403
01:04:29.180 --> 01:04:39.810
Diana Zuckerman: that were focused on these quality issues, and we thought that was really a problem, and we believe that that was resolved in the way that industry requested.

404
01:04:41.490 --> 01:04:45.299
Diana Zuckerman: I should also mention that on a meeting on May 14th,

405
01:04:46.322 --> 01:04:49.909
Diana Zuckerman: where there were some details

406
01:04:50.010 --> 01:04:54.750
Diana Zuckerman: about how FDA might use OMUFA fees to improve

407
01:04:55.040 --> 01:05:01.020
Diana Zuckerman: safety by improving educational resources and a database that includes warning letters,

408
01:05:01.380 --> 01:05:15.289
Diana Zuckerman: these are useful, but they don't really include the kind of metrics that we're looking for to ensure that safety and effectiveness is as important as speed

409
01:05:15.590 --> 01:05:19.310

Diana Zuckerman: in the way that OMUFA funds are used.

410
01:05:23.270 --> 01:05:26.219
Diana Zuckerman: According to the May 20

411
01:05:26.440 --> 01:05:44.029
Diana Zuckerman: meeting minutes, it seems that even those quality efforts were overruled. I may have misunderstood that, but that's what it seemed that the minutes showed because the industry counterproposal included the kinds of activities that don't directly benefit patients or consumers,

412
01:05:44.190 --> 01:05:47.019
Diana Zuckerman: such as new registrant vetting,

413
01:05:47.030 --> 01:05:49.649
Diana Zuckerman: targeted fee recovery efforts,

414
01:05:49.820 --> 01:06:07.970
Diana Zuckerman: and FDA holding a workshop on compliance. And I understand that it isn't fair if some companies aren't paying the fees that they're supposed to pay. I agree with that completely, but those are issues for industry to be concerned about, and for the FDA to be concerned about, and they don't directly help

415
01:06:08.230 --> 01:06:09.950
Diana Zuckerman: patients or consumers.

416
01:06:12.510 --> 01:06:25.130
Diana Zuckerman: As I mentioned, the minutes aren't very clear, so I may have misunderstood what exactly happened, and of course, I do want to say how pleased we are about the

417
01:06:27.110 --> 01:06:29.790
Diana Zuckerman: the process for any

418
01:06:31.660 --> 01:06:32.460
Diana Zuckerman: um. Oh.

419
01:06:33.660 --> 01:06:36.740
Diana Zuckerman: anything pertaining to safety issues.

420
01:06:36.910 --> 01:06:40.110

Diana Zuckerman: So we're glad that the timeline is faster

421
01:06:40.700 --> 01:06:44.170
Diana Zuckerman: than other reforms, and that the cost is free.

422
01:06:44.350 --> 01:06:54.259
Diana Zuckerman: And we're particularly glad that they can be initiated by the FDA. But what's not clear to us is whether FDA is going to have enough staff to do that.

423
01:06:54.470 --> 01:06:56.850
Diana Zuckerman: I also want to point out that

424
01:06:56.890 --> 01:07:15.779
Diana Zuckerman: nonprofit groups like ours can get into this process apparently through citizens petitions. But historically, that's been a very frustrating experience. And wouldn't it be great if OMUFA included some way that public health experts,

425
01:07:16.210 --> 01:07:20.289
Diana Zuckerman: consumer advocates, and others could

426
01:07:21.110 --> 01:07:24.520
Diana Zuckerman: initiate these changes

427
01:07:24.860 --> 01:07:31.329
Diana Zuckerman: in a way that's simpler from citizens petitions.
Nana Adjeiwaa-Manu: Dr. Zuckerman, you have about a minute left. Thank you.

428
01:07:32.042 --> 01:07:37.390
Diana Zuckerman: So, I think a lot of this really comes down to how much staff

429
01:07:37.510 --> 01:07:55.010
Diana Zuckerman: will the FDA have to work on these issues that focus on the safety and effectiveness, and not just on having more meetings with industry and speeding up the process of reviews that industry initiates.

430
01:07:55.150 --> 01:07:59.310
Diana Zuckerman: Dr. Brass mentioned the lack of incentives

431
01:07:59.420 --> 01:08:08.149

Diana Zuckerman: for industry to initiate safety reviews. And we're very concerned about that and want to make sure that there's more incentives

432
01:08:08.360 --> 01:08:15.590
Diana Zuckerman: and opportunities for the FDA to do that, and for other nonprofit organizations to do that.

433
01:08:16.069 --> 01:08:17.310
Diana Zuckerman: Thank you very much.

434
01:08:21.170 --> 01:08:23.100
Nana Adjeiwaa-Manu: Thank you, Dr. Zuckerman.

435
01:08:23.920 --> 01:08:46.769
Nana Adjeiwaa-Manu: We'll now move forward to hearing comments from members of the public who registered in advance of this meeting. I will call on each person individually, and they will have 5 minutes to give their remarks. I do apologize in advance if I mispronounce your name. At the 5-minute mark, I will ask you to conclude, and then I will introduce the next speaker.

436
01:08:46.770 --> 01:09:00.279
Nana Adjeiwaa-Manu: For those of you in person, you can come to the podium when I call your name. And for our virtual participants, please raise your hand when I call your name, and a member of our technical team will unmute you so that you can give your remarks.

437
01:09:00.330 --> 01:09:03.770
Nana Adjeiwaa-Manu: Please note that your camera will not be enabled.

438
01:09:04.720 --> 01:09:09.689
Nana Adjeiwaa-Manu: We will begin with Mark Scheineson. Mark, you may come up to the podium.

439
01:09:19.970 --> 01:09:21.609
Mark Scheineson: Thank you. Good morning.

440
01:09:21.640 --> 01:09:27.430
Mark Scheineson: My name is Mark Scheineson. I'm a partner in the Washington, DC. Office of the national

441
01:09:27.540 --> 01:09:34.290
Mark Scheineson: law firm of Alston & Bird. I'm also a former FDA Associate Commissioner for Legislative Affairs.

442
01:09:34.810 --> 01:09:39.109
Mark Scheineson: Our pharmaceutical clients include manufacturers, repackagers,

443
01:09:39.240 --> 01:09:42.020
Mark Scheineson: and wholesale distributors of prescription

444
01:09:42.040 --> 01:09:44.540
Mark Scheineson: and over-the-counter drug products.

445
01:09:45.300 --> 01:09:50.800
Mark Scheineson: I'm here today to briefly describe a technical glitch in the FDA's interpretation

446
01:09:50.890 --> 01:09:56.119
Mark Scheineson: of which facilities must pay the OTC drug user fee every year.

447
01:09:56.190 --> 01:09:59.310
Mark Scheineson: The OMUFA fee for each facility

448
01:09:59.400 --> 01:10:03.490
Mark Scheineson: is now at least $34,166

449
01:10:04.292 --> 01:10:06.280
Mark Scheineson: every year forever.

450
01:10:06.510 --> 01:10:10.420
Mark Scheineson: It is rising at a rate of approximately 30% a year.

451
01:10:11.180 --> 01:10:16.680
Mark Scheineson: Smaller companies, such as some I represent, are having a difficult time paying these fees,

452
01:10:16.890 --> 01:10:19.550
Mark Scheineson: especially when they simply repackage

453
01:10:19.650 --> 01:10:22.510
Mark Scheineson: or distribute OTC pharmaceuticals.

454

01:10:23.520 --> 01:10:27.070
Mark Scheineson: This downstream supply chain is frequently overlooked.

455
01:10:27.500 --> 01:10:32.319
Mark Scheineson: These companies are not thought of at all when drug manufacturing issues are discussed

456
01:10:32.540 --> 01:10:35.280
Mark Scheineson: and when statutory language is written.

457
01:10:36.080 --> 01:10:38.140
Mark Scheineson: Specifically, FDA

458
01:10:38.150 --> 01:10:39.270
Mark Scheineson: has been

459
01:10:39.590 --> 01:10:42.369
Mark Scheineson: imposing significant OMUFA fees

460
01:10:42.510 --> 01:10:48.319
Mark Scheineson: on repackaging facilities totally unrelated to the Pharma companies that make OTC drugs.

461
01:10:48.640 --> 01:10:53.469
Mark Scheineson: Many repackagers merely service smaller institutional pharmacies

462
01:10:53.640 --> 01:10:58.269
Mark Scheineson: and medical clinics by buying the expensive larger minimum quantities

463
01:10:58.610 --> 01:11:00.760
Mark Scheineson: required by the big 3

464
01:11:00.930 --> 01:11:03.070
Mark Scheineson: direct wholesale distributors.

465
01:11:03.790 --> 01:11:10.599
Mark Scheineson: The repackagers, for example, break down bottles of a thousand pills into smaller bottles of 100 pills

466
01:11:10.990 --> 01:11:15.410

Mark Scheineson: and quantities needed and affordable to these smaller pharmacies.

467
01:11:15.560 --> 01:11:19.209
Mark Scheineson: Some also repackage RX and OTC drugs

468
01:11:19.400 --> 01:11:25.190
Mark Scheineson: into unit doses for dispensing at the point of care to increase compliance.

469
01:11:25.590 --> 01:11:32.129
Mark Scheineson: This fee makes it difficult for repackagers, other than contract manufacturers for source manufacturers,

470
01:11:32.390 --> 01:11:36.500
Mark Scheineson: to justify carrying and handling OTC drug products.

471
01:11:36.690 --> 01:11:48.109
Mark Scheineson: This limits point of care access to patients seeking convenience, compliance, confidentiality, and cost savings. FDA is charging these companies annual OMUFA

472
01:11:48.340 --> 01:11:56.300
Mark Scheineson: facility fees simply because they register their establishments and list their products as required under the broad definition of manufacture

473
01:11:56.810 --> 01:11:59.969
Mark Scheineson: in 207.1 of the regulations.

474
01:12:00.540 --> 01:12:07.100
Mark Scheineson: Funny thing is that OMUFA does not even reference application of the manufacturer definition in 207.1.

475
01:12:07.180 --> 01:12:13.219
Mark Scheineson: Rather, it contains an entirely separate and narrower definition of OTC monograph drug facilities.

476
01:12:14.630 --> 01:12:22.220
Mark Scheineson: It is an OTC monograph facility that must pay the OMUFA fee, not a registered drug establishment.

477
01:12:22.380 --> 01:12:32.129

Mark Scheineson: That definition expressly excludes finished dosage for manufacturers who are not in a contractual relationship with any sponsor of OTC drugs

478
01:12:32.200 --> 01:12:34.589
Mark Scheineson: to manufacture or process

479
01:12:35.060 --> 01:12:36.520
Mark Scheineson: such drugs.

480
01:12:38.470 --> 01:12:39.949
Mark Scheineson: In other words,

481
01:12:40.030 --> 01:12:49.370
Mark Scheineson: a company that merely buys pills from Mckesson in a thousand count bottle and transfers them into a one hundred count bottle to sell to smaller pharmacies

482
01:12:49.440 --> 01:12:52.839
Mark Scheineson: should not be charged $34,000 a year. Why?

483
01:12:53.420 --> 01:13:10.800
Mark Scheineson: Because these smaller repackagers or secondary wholesale distributors down the distribution chain get absolutely no direct benefit from the new streamlined processes to modernize or revise OTC drug monographs for which OMUFA fees were designed to pay.

484
01:13:11.010 --> 01:13:12.760
Mark Scheineson: The law here is clear.

485
01:13:13.130 --> 01:13:15.759
Mark Scheineson: User fees cannot be taxes.

486
01:13:16.080 --> 01:13:20.730
Mark Scheineson: The payer must derive some significant benefit from the user fees it pays.

487
01:13:20.790 --> 01:13:30.189
Mark Scheineson: Which direct benefits do these repackagers or secondary wholesale distributors derive from hiring of more OTC drug reviewers?

488
01:13:30.790 --> 01:13:37.209

Mark Scheineson: Finally, and I'm wrapping up here, FDA defends its indefensible action to squeeze out

489
01:13:37.250 --> 01:13:44.359
Mark Scheineson: more money from these small secondary actors every year by attempting to argue that the plain meaning of the monograph

490
01:13:46.060 --> 01:13:47.480
Mark Scheineson: facility provision.

491
01:13:47.730 --> 01:14:03.730
Mark Scheineson: FDA argues unconvincingly and with that authority that the specific list of criteria in 744 l to become an OTC monograph drug facility does not require such a contractual relationship with an OTC drug sponsor.

492
01:14:04.000 --> 01:14:09.880
Mark Scheineson: If not required, why is the specific language included in the statute to define monograph facilities?

493
01:14:10.460 --> 01:14:18.309
Mark Scheineson: We believe it is required, and it is listed because Congress believed it would be unfair to assess such a large annual fee

494
01:14:18.350 --> 01:14:23.260
Mark Scheineson: from a company that did not actually work for the maker of the OTC drugs.

495
01:14:24.300 --> 01:14:42.329
Mark Scheineson: It is that maker and its business contractors which benefit from getting new formulations or expanded, labeled indications on OTC drug monographs, sorry, based on the new FDA reviewer salaries paid for

496
01:14:42.390 --> 01:14:43.520
Mark Scheineson: by these

497
01:14:43.610 --> 01:14:44.870
Mark Scheineson: user fees.

498
01:14:45.440 --> 01:14:51.750
Mark Scheineson: So for these reasons, we respectfully request that FDA clarify in guidance, or otherwise,

499
01:14:52.030 --> 01:14:59.000
Mark Scheineson: that these downstream supply chain facilities are not required to pay OMUFA facility fees.

500
01:14:59.540 --> 01:15:02.459
Mark Scheineson: Thank you for your attention and consideration.

501
01:15:03.620 --> 01:15:09.410
Nana Adjeiwaa-Manu: Thank you, Mark. Next, we will hear from Kim Wesick Kim, please come up to the podium.

502
01:15:23.180 --> 01:15:33.040
Kim Wezik: Thank you for the opportunity to provide comments to the FDA this morning. My name is Kim Wezik, and I'm the director of Advocacy for the Melanoma Research Foundation.

503
01:15:33.770 --> 01:15:42.629
Kim Wezik: We're the largest independent organization devoted to melanoma through our commitment to patient education, medical research, and advocacy.

504
01:15:43.150 --> 01:15:49.410
Kim Wezik: I'm here today to speak on behalf of the MRF and the Public Access to Sunscreens, or PAS, coalition,

505
01:15:49.610 --> 01:15:52.910
Kim Wezik: as well as the broader skin cancer patient community.

506
01:15:54.190 --> 01:16:04.319
Kim Wezik: I have the privilege of working with dedicated, passionate individuals whose lives have been upended by a melanoma diagnosis either for themselves or their loved ones.

507
01:16:04.810 --> 01:16:10.870
Kim Wezik: This is a disease that disfigures, kills, and financially exhausts real people.

508
01:16:10.950 --> 01:16:13.199
Kim Wezik: It is also largely preventable.

509
01:16:13.880 --> 01:16:24.190

Kim Wezik: According to the World Health organization, 4 out of 5 cases of melanoma or skin cancer can be prevented by adopting sun safe practices, such as wearing sunscreen.

510
01:16:25.350 --> 01:16:36.669
Kim Wezik: Many of my advocates share with me how they missed the opportunity to protect their skin and their youth before many of us were even aware of the deadly effects of ultraviolet exposure over a lifetime.

511
01:16:37.640 --> 01:16:47.099
Kim Wezik: They are steadfast in their advocacy to prevent melanoma and deeply concerned about the direction of public discourse and faith in public health surrounding sunscreen.

512
01:16:47.990 --> 01:16:51.970
Kim Wezik: The MRF and the PAS coalition share our advocates concerns.

513
01:16:52.190 --> 01:17:11.659
Kim Wezik: We have seen a rise in anti-sunscreen sentiments, particularly online, coupling vocal social media critics with the FDA's own messaging regarding which sunscreen filters are generally recognized as safe and effective presents a confusing and dangerous climate for any public health messaging related to sunscreen use.

514
01:17:12.520 --> 01:17:24.869
Kim Wezik: We wish to partner with the FDA and Congress to ensure the American people have the tools they need to keep themselves and their families safe and restore faith in sunscreen as a cancer prevention tool.

515
01:17:25.180 --> 01:17:33.689
Kim Wezik: In order to accomplish those goals, we must have good sunscreen policy as our foundation, including finding a way forward on testing standards

516
01:17:33.820 --> 01:17:36.720
Kim Wezik: and finding a way forward on animal testing.

517
01:17:38.190 --> 01:17:49.040
Kim Wezik: Over a decade ago, various stakeholders came together to form the PAS coalition in an effort to protect Americans from skin cancer, including the deadliest form of skin cancer, melanoma,

518
01:17:49.080 --> 01:17:57.099
Kim Wezik: by increasing access to safe and effective sunscreens and promoting evidence-based education on sun safe practices.

519
01:17:57.900 --> 01:18:09.169
Kim Wezik: Since that time, the PAS coalition has worked with policymakers at both the FDA and Congress to address gaps in sunscreen policy that leave Americans vulnerable to skin cancer.

520
01:18:09.680 --> 01:18:22.200
Kim Wezik: With the passage of the Sunscreen Innovation Act of 2014, we hope to usher in a new era of skin cancer prevention, streamlining the sunscreen filter approval process, and increasing the number of filters available

521
01:18:22.260 --> 01:18:26.189
Kim Wezik: for a variety of skin textures, tones, and conditions.

522
01:18:26.940 --> 01:18:50.310
Kim Wezik: Unfortunately, we find ourselves today at risk not just of stymied progress, as no new filters have been approved in the United States since the 1990s, but regression in the form of fewer available sunscreen filters should the FDA finalize a proposed order that would leave the country with only 2 sunscreen, active ingredients, generally recognized as safe and effective, due to those additional testing requirements.

523
01:18:51.930 --> 01:19:05.940
Kim Wezik: The American people rely on the FDA to keep us safe, but a failure to approve new sunscreen filters, however well-intentioned the logic behind additional testing may be, leaves us vulnerable to unnecessary skin cancer diagnoses.

524
01:19:06.130 --> 01:19:13.040
Kim Wezik: We urge the FDA and sunscreen manufacturers to work together towards a solution that moves approvals forward.

525
01:19:14.480 --> 01:19:27.719
Kim Wezik: Particularly as the human cost of skin cancer diagnoses continues to increase, with the American Cancer Society, expecting the number of new melanoma diagnoses to increase by 7.3% this year,

526
01:19:27.900 --> 01:19:31.259
Kim Wezik: and the number of deaths to increase by 3.8%.

527
01:19:32.010 --> 01:19:42.730

Kim Wezik: We urge the FDA to address these concerns in their OMUFA reauthorization recommendations to Congress, and we welcome the opportunity to serve as a resource for the FDA. Thank you.

528
01:19:43.890 --> 01:19:48.980
Nana Adjeiwaa-Manu: Thank you, Kim. Now we will hear from Rafael Ngendakumana.

529
01:19:49.110 --> 01:19:55.079
Nana Adjeiwaa-Manu: Raphael, please raise your hand via Zoom, and a member of our AV team will unmute you.

530
01:20:04.500 --> 01:20:06.330
Nana Adjeiwaa-Manu: Is Raphael on the line?

531
01:20:11.850 --> 01:20:12.620
Nana Adjeiwaa-Manu: Okay.

532
01:20:13.390 --> 01:20:19.809
Nana Adjeiwaa-Manu: Hearing nothing, I'll move forward to our next speaker. We have remarks from Samantha Wigglesworth.

533
01:20:19.850 --> 01:20:26.540
Nana Adjeiwaa-Manu: Samantha, please raise your hand via Zoom, and a member of our AV team will unmute you so that you can give your comment.

534
01:20:37.340 --> 01:20:39.639
Nana Adjeiwaa-Manu: Samantha Wigglesworth, are you on the line?

535
01:20:45.670 --> 01:20:49.339
Nana Adjeiwaa-Manu: Moving forward, we will now hear from Samantha Sears.

536
01:20:49.450 --> 01:20:54.550
Nana Adjeiwaa-Manu: Samantha, please raise your hand via Zoom, and a member of our AV team will unmute you.

537
01:21:04.270 --> 01:21:07.350
Nana Adjeiwaa-Manu: I see that one person has their hand raised.

538
01:21:07.720 --> 01:21:11.669
Nana Adjeiwaa-Manu: Is our AV team able to unmute the attendees?

539

01:21:18.060 --> 01:21:20.930
Nana Adjeiwaa-Manu: Please bear with us for just a moment.

540
01:21:21.190 --> 01:21:25.759
Nana Adjeiwaa-Manu: I see that their hands are raised, but I'm not sure if our A/V Team is able to unmute them.

541
01:21:25.760 --> 01:21:27.379
Samantha Sears: Hello! Can you hear me?

542
01:21:27.850 --> 01:21:30.840
Nana Adjeiwaa-Manu: Yes, we can hear you. Could you please state your name?

543
01:21:30.840 --> 01:21:33.170
Samantha Sears: Wonderful. My name is Samantha Sears.

544
01:21:33.960 --> 01:21:35.540
Nana Adjeiwaa-Manu: Thank you. Please begin.

545
01:21:36.220 --> 01:21:50.010
Samantha Sears: The National Consumers League first would like to commend FDA for holding this public meeting to gather stakeholder feedback on the OMUFA reauthorization. As I mentioned, my name is Samantha Sears,

546
01:21:50.180 --> 01:22:00.470
Samantha Sears: and I am the Health Policy Associate here at NCL. Founded in 1899, the National Consumers League is America's pioneer consumer organization.

547
01:22:00.470 --> 01:22:25.600
Samantha Sears: NCL provides government, business, and other organizations with consumer perspectives on several concerns and topics, such as fraud, child labor, food, safety, and workforce protections. Among NCL’s top priorities are ensuring the safety, effectiveness, and appropriate use of medications, both prescription and over-the-counter, as well as adherence to that medication which we've advanced and focused on through our script to your future campaigns.

548
01:22:25.670 --> 01:22:42.909
Samantha Sears: NCL has previously provided testimony in 2016 on the benefits of OMUFA, expressing our support for the program, as well as well as providing specific recommendations for performance goals, such as commitment to initiating a certain number of finalizations a year.

549
01:22:43.640 --> 01:23:11.790
Samantha Sears: Given that the legislative authority of OMUFA expires at the end of September of 2025, we encourage FDA to continue to work on the longstanding proposed orders that have been in process for nearly 3 years now. Specifically, there are 2 proposed orders on the FDA OTC monograph annual forecast, which NCL would like to encourage the agency to focus on and finalize before the legislative authority of OMUFA expires.

550
01:23:11.790 --> 01:23:23.560
Samantha Sears: NCL recommends that FDA address the generally recognized as safe and effective status of coding active ingredients in cough medicines, and to officially remove it from the OTC monograph.

551
01:23:23.560 --> 01:23:47.590
Samantha Sears: This FDA-initiated proposed order was first listed in September 2022 and has not yet been addressed. Medication with codeine is no longer available without a prescription, and FDA began evaluating the risks of codeine cough medicine in 2015. Overall, NCL does not anticipate that addressing the GRASE of codeine active ingredients in cough medicine

552
01:23:47.600 --> 01:23:58.430
Samantha Sears: and removing it from the OTC monograph would require a major change or a tremendous amount of extra work from the agency.

553
01:23:59.250 --> 01:24:08.560
Samantha Sears: Additionally, NCL recommends that FDA also address the dosage strengths of oral, single ingredient, pediatric acetaminophen production,

554
01:24:08.700 --> 01:24:38.350
Samantha Sears: including the addition of weight and age-based dosing for children under 12 years old. Addressing this proposed order, which was also first listed in September of 2022 would align with the work currently being undertaken within FDA's Division of Non-Prescription Drugs I, as the division just hosted a workshop on non-prescription, pain and fever development in children under 12 years old, where NCL had the opportunity to provide comments

555
01:24:38.840 --> 01:25:03.069
Samantha Sears: on the consumer perspective. We commend the FDA for soliciting the views of many stakeholders who have a vested interest in OTC medication and the OMUFA program. We especially appreciate giving consumer organizations an opportunity to share our views. We look forward to continuing to work with FDA and the OTC industry on reauthorizing this user fee program. Thank you for your time today.

556

01:25:04.140 --> 01:25:14.190
Nana Adjeiwaa-Manu: Thank you, Samantha, and Samantha Wigglesworth, we see that you're on the line. Samantha, please raise your hand via Zoom, and a member of our AV team will unmute you.

557
01:25:17.640 --> 01:25:19.470
Samantha Wigglesworth: Oh, hi there. Thank you.

558
01:25:22.340 --> 01:25:24.080
Nana Adjeiwaa-Manu: Hi, Samantha, you may begin.

559
01:25:25.619 --> 01:25:32.929
Samantha Wigglesworth: Thank you for today's panel discussion regarding OMUFA reauthorization

560
01:25:32.940 --> 01:25:52.839
Samantha Wigglesworth: and the fee program. I'm a founder myself and CEO of an organization called Girls and Boys in Tech that focuses on improving health outcomes for women and girls in the cancer areas and also in mental health.

561
01:25:53.080 --> 01:25:53.760
Samantha Wigglesworth: Oh.

562
01:25:55.150 --> 01:26:04.039
Samantha Wigglesworth: Very positively, you know, the outcomes of the OMUFA program, the reauthorization program, as a consequence of the Care Act funding,

563
01:26:04.571 --> 01:26:07.459
Samantha Wigglesworth: is very positive from my perspective.

564
01:26:07.630 --> 01:26:13.769
Samantha Wigglesworth: I'm looking forward to seeing how the new hires, the researchers, and the scientists are being onboarded

565
01:26:14.960 --> 01:26:22.559
Samantha Wigglesworth: in moving this program forward to a more safe and efficacy led over-the-counter

566
01:26:23.375 --> 01:26:24.120
Samantha Wigglesworth: program.

567

01:26:24.898 --> 01:26:33.980
Samantha Wigglesworth: I think, obviously, the developments from other safety standards have been really enlightening, specifically around the skin reaction

568
01:26:34.120 --> 01:26:38.230
Samantha Wigglesworth: issue that was cited earlier on in the discussions,

569
01:26:38.390 --> 01:27:01.530
Samantha Wigglesworth: and how that will impact and improve outcomes for patients and for consumers. I do think it's important as well as raised, that the FDA works closely with industry, and it is great to see that education element being introduced, and that is something, certainly, that I think will be very beneficial to consumers across

570
01:27:02.190 --> 01:27:03.489
Samantha Wigglesworth: the industry.

571
01:27:03.760 --> 01:27:13.270
Samantha Wigglesworth: Workshops are key, as is access to appropriate research-led, and scientific information, as well as historical data.

572
01:27:14.242 --> 01:27:19.869
Samantha Wigglesworth: I do think, as well, the availability of better information,

573
01:27:19.910 --> 01:27:38.679
Samantha Wigglesworth: documentation, and transparency of such orders, for example, and historic rulings, is absolutely fundamental. And that's great to see from the developments of the database paper documentation and the web pages that are being uploaded and being produced at the moment.

574
01:27:38.680 --> 01:27:50.640
Samantha Wigglesworth: And I think also, with regards to the panel discussions, you know, discussions around the interactions between FDA and industry, whether

575
01:27:52.000 --> 01:28:00.819
Samantha Wigglesworth: is fundamental. Long meetings are necessary, as was highlighted, especially when it comes to research in OTC medication

576
01:28:00.880 --> 01:28:27.819

Samantha Wigglesworth: and ensuring efficacy and safety. I do think innovation is key, and I particularly think the discussions around reductions in fees for those sites that are focusing on innovations in drug development is a positive move, certainly, and the greater oversight of the sites that are both in compliance with regulations and also in arrears, is a very good move.

577
01:28:27.910 --> 01:28:33.109
Samantha Wigglesworth: I think that will lend itself to a more rigorous, risk-based approach…

578
01:28:34.630 --> 01:28:39.770
Samantha Wigglesworth: Sites that are most appropriate for consumer safety and public safety.

579
01:28:40.020 --> 01:28:47.419
Samantha Wigglesworth: I do also welcome the comments from other panelists around the importance of

580
01:28:47.470 --> 01:28:48.780
Samantha Wigglesworth: having,

581
01:28:49.490 --> 01:29:07.779
Samantha Wigglesworth: you know, the virtual meeting format, so that more stakeholders can be involved, that we have more timely and transparent development, and have regular meetings to understand better the needs of drug design organizations and manufacturers, specifically around study design programs.

582
01:29:08.478 --> 01:29:10.570
Samantha Wigglesworth: And I also think that obviously

583
01:29:10.840 --> 01:29:24.940
Samantha Wigglesworth: the GRASE standards is key as well, and there is not necessarily a need to reproduce old standards and rulings, and that an awareness of that is important.

584
01:29:25.805 --> 01:29:29.494
Samantha Wigglesworth: Yeah, thank you very much, and I welcome the comments from

585
01:29:29.970 --> 01:29:36.070
Samantha Wigglesworth: the academic and advocacy panel around the importance of a focus on public health,

586
01:29:36.270 --> 01:29:47.449
Samantha Wigglesworth: and really looking forward to seeing how OMUFA reauthorization can move towards safer standards, particularly in pediatric over-the-counter medication for children.

587
01:29:47.807 --> 01:29:50.880
Samantha Wigglesworth: Thank you for your time and thank you for listening.

588
01:29:52.770 --> 01:29:54.569
Nana Adjeiwaa-Manu: Thank you, Samantha.

589
01:29:54.620 --> 01:30:03.989
Nana Adjeiwaa-Manu: Manish Sabharwal will now give a public comment. Manish, if you're on the line, please raise your hand via Zoom, and a member of our AV. Team will unmute you.

590
01:30:11.290 --> 01:30:13.800
Nana Adjeiwaa-Manu: All right, we'll move forward.

591
01:30:14.240 --> 01:30:20.220
Nana Adjeiwaa-Manu: We will now hear from Forrest Ford. Forrest, if you're in the room with us, you may please come up to the podium.

592
01:30:24.530 --> 01:30:25.210
Nana Adjeiwaa-Manu: Okay.

593
01:30:26.380 --> 01:30:28.230
Nana Adjeiwaa-Manu: Moving forward here,

594
01:30:28.550 --> 01:30:37.060
Nana Adjeiwaa-Manu: we have remarks from Adeela Salih. Adeela, if you're on the line, please raise your hand via Zoom, and a member of our team will unmute you.

595
01:30:42.350 --> 01:30:43.900
Nana Adjeiwaa-Manu: We'll move forward here.

596
01:30:44.500 --> 01:30:53.929
Nana Adjeiwaa-Manu: Vishnu Vardhan Tinnaluri will now give a public comment. Vishnu, if you're on the line, please raise your hand via Zoom, and a member of our AV team will unmute you.

597
01:30:58.130 --> 01:31:07.670
Nana Adjeiwaa-Manu: We'll move forward here. Next, we'll hear from Richard Floyd. Richard, if you're on the line, please raise your hand via zoom, and a member of our AV team will unmute you.

598
01:31:11.010 --> 01:31:12.580
Nana Adjeiwaa-Manu: Alright. We'll move forward.

599
01:31:12.920 --> 01:31:21.280
Nana Adjeiwaa-Manu: We will now hear remarks from Carlos Crespo Pérez. Carlos, please raise your hand via Zoom, and a member of our AV team will unmute you.

600
01:31:24.400 --> 01:31:35.450
Nana Adjeiwaa-Manu: All right. We'll move forward here. Affan Ali will now give a public comment Affan, if you're on the line, please raise your hand via Zoom, and a member of our AV team will unmute you.

601
01:31:39.530 --> 01:31:48.719
Nana Adjeiwaa-Manu: And finally, we have remarks from Chesie Voma. Chesie, if you're on the line, please raise your hand via Zoom, and a member of our AV Team will unmute you.

602
01:31:50.880 --> 01:31:51.840
Nana Adjeiwaa-Manu: All right.

603
01:31:52.380 --> 01:32:05.150
Nana Adjeiwaa-Manu: So that concludes comments from the members of the public. Thank you for your feedback. We will now wrap up the presentations with remarks from Theresa Michelle, Director of FDA's Office of Non-Prescription Drugs.

604
01:32:13.560 --> 01:32:16.249
Theresa Michele: Yeah, I get to move the mic down because I'm short.

605
01:32:17.280 --> 01:32:26.229
Theresa Michele: So, thank you once again everyone for being here today. We got a lot of important feedback, and I think some of the themes that I heard resonate

606
01:32:26.390 --> 01:32:30.489
Theresa Michele: were, of course, how important this OMUFA program is.

607

01:32:30.670 --> 01:32:50.939
Theresa Michele: Important for industry, the ability to innovate, the ability to see things move, the ability to meet with FDA. We heard time and time again about how critical those development meetings are, and the feedback that you obtain from meeting with our reviewers.

608
01:32:52.460 --> 01:32:58.869
Theresa Michele: The other thing that I heard resonate was the importance for consumers

609
01:32:59.010 --> 01:33:09.049
Theresa Michele: and for public health of this program, the ability to hear from consumers through the public comment periods, and

610
01:33:09.260 --> 01:33:35.000
Theresa Michele: this is also critical for small businesses who may not have the facilities to submit an OMOR to be able to participate in that process. So, it's exciting that this, that one of the nice things about OMUFA is that it did preserve that public input that I think is so critical to a really robust monograph program for OTC drugs.

611
01:33:36.200 --> 01:34:02.940
Theresa Michele: And finally, we heard about the need for this to be a lean program from industry because companies, particularly small businesses, are working on small margins. And so, they want to make sure that the dollars that are spent towards this are spent efficiently. And of course, we all share that goal to make sure that we are doing the most with what we have.

612
01:34:04.130 --> 01:34:09.339
Theresa Michele: Importantly, though, we need to focus on safety and effectiveness.

613
01:34:09.530 --> 01:34:26.599
Theresa Michele: That's important to consumers, it's important to industry, and it's important to all of us who take these medications, and I know personally, I have a number of them on my medicine shelf, and I bet every single person in this room, and who is listening virtually

614
01:34:26.600 --> 01:34:43.699
Theresa Michele: have some as well. So, we all have a vested interest in making this program successful. I appreciate all of you for being here today, for providing your remarks. We'll certainly take them under advisement as we progress in this negotiation process.

615
01:34:44.020 --> 01:35:04.460

Theresa Michele: And for those of you who may not have had an opportunity to comment yet, the docket is still open. Please do submit your comments. We want to hear from you. So, with that I'll close out our meeting. Thank you again for coming. Do take some water on your way out, and don't drink from the fountains, so have a great day.