DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Administrative Detention of Drugs Intended for Human or Animal Use; Final Rule

Docket No. FDA-2013-N-0365

Final Regulatory Impact Analysis
Final Regulatory Flexibility Analysis
Unfunded Mandates Reform Act Analysis

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I. Introduction and Summary

A. Introduction

FDA has examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612) and the Unfunded Mandates Reform Act of 1995 (Public Law 104-4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Agency believes that this final rule will not be an economically significant regulatory action as defined by Executive Order 12866.

If a rule has a significant economic impact on a substantial number of small businesses, the Regulatory Flexibility Act requires Agencies to analyze regulatory alternatives that would minimize any significant impact of a rule on small entities. FDA has determined that this final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $141 million, using the most current (2012) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that will meet or exceed this amount.

B. Summary of Costs and Benefits

The final rule will give FDA the authority to order a drug detained for a limited period of time if during an inspection there is reason to believe the drug is adulterated or misbranded. Since the administrative detention of drugs is a new enforcement tool, we are not able to directly estimate how often it will be used. Instead, we assume that events that trigger certain existing enforcement or regulatory actions represent a pool of events, some of which might trigger administrative detention. Voluntary recalls and seizures are two types of actions that FDA might use in similar circumstances to those in which it might use its administrative detention authority for drugs. We have used certain costs associated with these actions to estimate the number of times FDA will use its administrative detention authority to detain drugs.

The primary public health benefits from adoption of the final rule will be the value of the illnesses or deaths prevented because the Agency administratively detained a drug it has reason to believe is adulterated or misbranded; these benefits occur only if the drug will not have been prevented from entering the market using one of the Agency's other enforcement tools. There will also be benefits from deterrence if administrative detention increases the likelihood that misbranded or adulterated products will not be marketed in the future.

Table 1 – Summary of Costs

		Low Estimate	High Estimate
	Annual Net Social Costs	$0	$602,602
Present Value of Discounted Social Costs	3% Discount Rate	**$0**	**$8,965,196**
	7% Discount Rate	**$0**	**$6,383,974**

The estimated primary costs to FDA include marking or labeling the detained product and costs associated with appeals of detention orders. However, other costs, such as loss in market value of a detained drug, will be incurred if FDA revokes the detention order on appeal. Given the history of administrative detention use with medical devices and foods, the likelihood is low of FDA issuing a detention order that is later revoked on appeal.

The net annual costs to society of the final rule are summarized in Table 1. We estimate the annual costs using a range of 0 to 20 administrative detentions performed each year. The Agency estimates the net annual social costs to be between $0 and $602,602. The present discounted value over 20 years will be in the range of $0 to $8,965,196 at a 3 percent discount rate and in the range of $0 to $6,383,974 at a 7 percent discount rate.

II. Final Regulatory Impact Analysis

A. Need for Regulation

The final rule will implement FDA's authority to order a drug detained for a limited period of time if there is reason to believe the drug has been adulterated or misbranded. This authority will provide an added measure to ensure the safety of the nation's drug supply. Current enforcement methods, such as seizures, will take additional time to execute because the matter needs to be filed in court or, in the case of voluntary recalls, due to the need for coordination with the firms that own the products. Administrative detention will be temporary, but will prevent the distribution or use of drugs that FDA has reason to believe are adulterated or misbranded until FDA has had time to consider what action it will take concerning the drugs, and to initiate legal action, such as seizure, if appropriate. Administrative detention for drugs is particularly attractive for cases where there is a high likelihood that the drug will be moved or will enter commerce before another enforcement tool can be applied.

Section 709 of Title VII of Food and Drug Administration Safety and Innovation Act (FDASIA) amends section 304(g) of the FD&C Act to authorize the administrative detention of drugs that FDA has reason to believe are adulterated or misbranded. As with the current detention authorities granted to FDA, the final rule will implement FDA's authority to detain drugs intended for human or animal use that are believed to be adulterated or misbranded for up to 30 calendar days. Any person who is entitled to claim a detained drug if it were seized may appeal the detention order. FDA must confirm the detention or revoke the order within 5 days of the date that the appeal is filed with FDA, after having given the appellant an opportunity for an informal hearing.

B. Baseline Conditions

The final rule will allow an authorized FDA representative to detain a drug if there is reason to believe the drug is misbranded or adulterated. In order to estimate the net economic impact of this final rule on society, an approximation of the change in behavior of consumers, producers, and FDA is needed. The effects of the final rule are estimated relative to a baseline. The baseline represents the state of the world in the absence of the final regulatory action. The current state of regulatory authority over adulterated or misbranded drugs is the baseline in those analyses. Currently, FDA will, among other actions, move to seize an adulterated or misbranded drug, work with the firm on a voluntary recall, or, depending on applicable state law, request that states place an embargo on the drugs. We assume FDA will use the final administrative detention enforcement tool prior to another type of action. Therefore, the impact of the final rule can only be realized in the cases where FDA chooses to use the administrative detention tool in addition to using any of the other enforcement or regulatory tools available.

To analyze the impact of the final rule, we first estimate how many times we might use administrative detention. We do not know how often we will encounter situations where officers or employees conducting an inspection will have reason to believe drugs are adulterated or misbranded such that we will order the drugs detained. One way of addressing the question is to approximate the number of times administrative detention could be used based on the number of times other enforcement or regulatory tools are currently used. Two types of actions that could be used in circumstances similar to administrative detention are seizure and voluntary recall (or requiring a recall in the case of biologics).

Table 2 presents the numbers of drug seizures and voluntary class I recall events over the last five fiscal years by FDA Center. Seizures and voluntary class I recalls are enforcement options frequently used when consumption of or exposure to the violative product by the consumer may result in an adverse health consequences or death. Administrative detention gives the Agency a tool that is quicker to implement and can be used to respond to these issues before a voluntary recall or seizure can be effected. Therefore, we use the number of seizures and voluntary class I recalls as our baseline. Over the 5-year period, there have been a total of 12 seizures and 215 voluntary class I recall events. This averages to 2.4 seizures and 43 voluntary class I recall events per year.

Another way of estimating the number of times FDA may use its administrative detention authority is to look at the number of times administrative detention has been used for medical devices and foods. In the past decade, FDA has used this enforcement tool in 0 medical device cases and 7 food cases.

There is no reason to expect administrative detention will be used more or less often for drugs than it is currently used for medical devices (none in the past decade) and foods (7 times over two years). Therefore, we approximate administrative detention of drugs will not be used more than 20 times per year. The lower bound is zero because we may not use administrative detention for drugs during the year.

Table 2 – Seizures and Class I Recalls by Fiscal Year

Center	Enforcement	FY 2009	FY 2010	FY 2011	FY 2012	FY 2013
CBER	Seizure	0	0	0	0	0
	Class I Recall	0	0	0	0	0
CDER	Seizure	3	3	3	2	1
	Class I Recall	30	29	43	28	46
CVM	Seizure	0	0	0	0	0
	Class I Recall	1	3	7	9	19

C. Benefits of the Final Rule

Adopting the final rule will provide FDA with another enforcement tool to better protect the nation's drug supply chain. Primary benefits to society include the value of additional illnesses or deaths prevented by administrative detention compared with other enforcement and regulatory actions that are currently available. This new authority will allow FDA to prevent the movement of drugs if there is reason to believe that the drug is adulterated or misbranded. Our analysis assumes FDA will likely only choose administrative detention in cases where it is the most effective enforcement tool available in a particular situation.

Administrative detention differs from seizures and voluntary class I recalls in the speed of action, need for coordination, and timeframe. Administrative detention can be implemented more quickly than a seizure and a voluntary recall, which generally involves some coordination between FDA and third parties. However, administrative detention cannot exceed 30 calendar days. Often, a voluntary recall or a more permanent mechanism for keeping an adulterated or misbranded drug from being distributed, such as a seizure, will also be required in order to keep the drug from being distributed. Actions that we can implement faster will reduce risk more than actions that take longer to implement because we have a higher probability of removing the drug from commerce before it reaches the consumer.

We are unable to estimate the potential annual benefits because this final rule addresses low probability but potentially high risk events. These events do not occur regularly, and we have insufficient information to predict their occurrence. Without knowing the likelihood or cost of an event, we cannot quantitatively measure the reduction in probability of an event occurring or the possible reduction in cost of an event associated with each regulatory option.

However, our use of the administrative detention authority for foods does provide some insight into possible benefits of the enforcement tool. FDA's Center for Food Safety and Applied Nutrition (CFSAN) has used administrative detention to stop violative products from entering commerce seven times since being given administrative detention authority in 2011. FDA has detained over 225,000 pounds of food and a retail value of over $8,000,000 in dietary supplements. Assuming a conservative estimate of usage of 0.5 pounds of food per person, it is possible that over 450,000 people were kept from consuming contaminated food.

D. Costs of the Final Rule

The final rule will result in increased costs to FDA. We analyze the cost of administrative detention actions relative to the baseline of taking the actions we would have taken prior to having received this authority to take administrative detention actions. Therefore, only the costs that go beyond the costs of moving directly to seizure or a voluntary class I recall are relevant here. We then multiply the changes in costs by the number of times we order an administrative detention.

The primary costs of the final rule arise from differences between administrative detention and other types of actions, specifically voluntary class I recalls and moving directly to seizures, with respect to the cost of marking or labeling the detained drug and the cost of participating in the appeals process. It is likely that we follow an administrative detention with another action, such as a seizure or voluntary class I recall. Therefore, costs presented in this analysis are the added costs of administratively detaining the drug before a seizure or voluntary class I recall.

Other potential costs will be incurred by industry and FDA if FDA revokes the detention order on appeal, and the drug is subsequently released. As mentioned earlier, given FDA's history of administrative detention use, there is a low likelihood that a detention order will be revoked on appeal.

1. Costs of Labeling or Marking the Detained Drug

Drugs that have been administratively detained will be labeled or marked with official FDA tags by an FDA representative. As discussed in the final rule for the administrative detention of foods in 2003, the detained product will be labeled or marked in several ways, including, but not limited to, affixing a tag having a self-locking pin that will be inserted in an appropriate seam, border, flap, or other area of the container or product; taping or tying a tag firmly onto the container or item; or affixing the tag to the accompanying documents, or to the carrier (68 FR 25242). Currently, moving directly to seizure will result in marking, or activity similar to marking, such as taking inventory, by the U.S. Marshall enforcing the seizure. However, working with the firm on voluntary class I recalls does not require the marking of the potentially violative product by FDA. As a result, the baseline labeling or marking cost for a voluntary class I recall action is $0. The marking performed by FDA in the event of an administrative detention prior to a seizure represents a transfer of costs and is not included in this analysis.

The cost associated with labeling or marking the detained drug includes costs for materials and the FDA representative's time. Although the detained drugs must be labeled or marked with official FDA tags, there is no requirement on the technique the FDA representative will choose. For instance, the agent will label each package individually or wrap several packages together in plastic and use only one label. Using information about the products seized over the 5-year period presented in Table 2, we estimate there were approximately 900 cases (or drums) per seizure. There will be instances where individual drug products are outside of a case. The FDA representative will then choose to label each product or lump several together. Over

the same 5-year period in cases where not all seized products were in cases, each seizure averaged 3,300 individual drug products.

We estimate the cost of materials based on the cost of creating each label. The cost of creating a label varies by size of the label, formatting on the label, and type of label used. We assume the label will be printed with black ink on one standard sheet of white printer paper and affixed to each detained case with tape. Given the information required to be printed on the label, we estimate FDA can print 4 labels on each sheet of paper if individual drug products must be marked as detained. A search of personal printers and commercial printing shops reveals a market price of approximately 5 cents per page. If it is possible to wrap all detained products in plastic and use only 1 label, it will cost FDA approximately $0.05 (= $0.05 per label * 1 label) per detainment. If each case must be labeled or marked and there are 900 cases in each detainment, it will cost FDA $46 (= $0.05 per label * 900 cases) per detainment to label or mark each case. If there are individual drug product that must also be marked, it will cost FDA approximately $42 (= $0.05 per label / 4 labels per page * 3,300 individual drug products) per detainment to label or mark each drug product. Given this information, FDA estimates it will cost between $0.05 and $88 (= $46 + $42) to print the labels needed to mark each detained shipment.

We estimate the value of an FDA representative's time based on the hourly wage rate of a GS-10, step 5 employee, plus 100 percent benefits and overhead. The 2012 General Schedule Base Pay for this inspector was approximately $25 per hour (Ref. 1). Including benefits and overhead gives an hourly rate of $50 (= $25 * 2). We assume an individual can attach 100 labels per hour. If it is possible to wrap all detained products in plastic and use only 1 label, it will take the FDA representative 0.01 hours (= 1 label / 100 labels per hour) to mark each detained shipment at a cost of $0.50 (= $50 per hour * 0.01 hours). If each case must be labeled or marked and there are 900 cases in each detention, it will take the FDA representative 9 hours (= 900 cases / 100 labels per hour) to label each detained shipment. We estimate it will cost $450 (= $50 per hour * 9 hours) to label or mark each detained case. If there are individual drug products along with the cased drug products that must be labeled or marked and there are 3,300 non-cased products in each detention, it will take the FDA representative 33 hours (= 3,300 cases / 100 labels per hour) to label each detained shipment. We estimate it will cost $1,650 (= $50 per hour * 33 hours) to label or mark each detained product. Given this information, FDA estimates it will cost between $0.50 and $2,100 (= $450 + $1,650) to physically mark each detained shipment.

The cost to label or mark each detained shipment will depend on the size of the shipment and the FDA representative's method of labeling the detained shipment. Using one label to mark the entire detained shipment will cost FDA $0.55 (= $0.05 in materials + $0.50 in time) per detention. Marking each individual case and any non-cased products will cost FDA $2,188 (= $88 in materials + $2,100 in time) per detention.

As we mentioned earlier, the marking performed by FDA in the event of an administrative detention prior to a seizure represents a transfer of costs and is not included in this analysis. Instead, we only use the difference in marking costs between a voluntary class I recall and an administrative detention. Therefore, we need to consider how many of the projected

administrative detentions will occur prior to a voluntary class I recall or a seizure. Over the 5-year period of seizure and recall actions presented in Table 2, class I recalls represent 95 percent of the actions taken and seizures represent 5 percent. Projecting these percentages on our estimated range of administrative detention actions that will be contested gives up to 19 (= 20 contested administrative detentions * 95 percent) class I recalls being preceded by administrative detentions and up to 1 (= 20 contested administrative detentions * 5 percent) seizures being preceded by an administrative detention.

We estimate the time cost of marking the administratively detained drug in the range $0 (= 0 detained shipments * $0.55 per shipment) to $41,572 (= 19 detained shipments * $2,188 per shipment).

2. Costs of Appealing an Administrative Detention

FDA will also incur costs associated with the owner of a detained drug contesting the detention of their product by FDA. The costs associated with the appeals process of an administrative detention will be considered relative to costs of the appeals process for other enforcement and regulatory tools. Class I drug recalls are voluntary actions taken by the firm and therefore there is no appeals process associated with class I recalls. However, firms can contest seizure actions. Firms who contest an administrative detention and lose that appeal are probably less likely to contest a subsequent seizure action, than firms that are involved in a seizure action that was not preceded by an administrative detention. Therefore, the appeals process for administrative detentions will, as a practical matter, replace the process of contesting seizure actions in many cases in which we administratively detain a drug and then seize it.

The administrative detention of foods rule estimated it will cost FDA approximately $50,000 to $70,000 for costs related to appeals of administrative detention in 2003 dollars. Updating to 2012 prices gives us a range of approximately $61,000 to $86,500 per detention appeal. This estimate is based on FDA's costs for preparing for possible appeals, which will be generated by all administrative detention actions, and our costs for participating in and conducting appeals hearings, which will be generated only by those administrative detentions that result in hearings. Therefore the incremental change in appealing an administrative detention relative to a class I recall will be approximately $61,000 to $86,500 per appealed administrative detention.

Since seizures can be contested through a formal process, to calculate the additional cost of preceding a seizure with an administrative detention order we subtract FDA's cost for preparing for and participating in a contested seizure action from FDA's cost for preparing for, participating in, and conducting a contested administrative detention action. The administrative detention of foods rule estimated it costs FDA approximately $10,000 to $20,000 for activities related to seizure appeals in 2003 dollars. Updating to 2012 prices gives us a range of approximately $12,200 to $25,500 in costs per seizure appeal. Therefore the incremental change in appealing an administrative detention relative to a seizure will be approximately $35,500 (= $61,000 per administrative detention hearing - $25,500 per seizure appeal) to $74,300 (= $86,500 per administrative detention hearing - $12,200 per seizure appeal) per appealed administrative detention.

Before we total the costs of appealing an administrative detention we must consider two additional factors. First, not all administrative detention orders will be appealed. None of the 7 CFSAN administrative detentions mentioned in Section II.B resulted in an informal hearing. A way to get a reasonable estimation of the percentage of administrative detentions that will be appealed is to look at the percentage of seizures that are contested. Recently, approximately 10 percent of seizures have been contested. Using this rate gives us a total number of 2 (= 20 administrative detentions * 10 percent of seizures contested) administrative detentions that will be contested each year, on average.

Second, we need to consider how many of the projected administrative detentions that are contested will be prior to a voluntary class I recall or a seizure. As mentioned earlier, voluntary class I recalls represent 95 percent of the actions taken and seizures represent 5 percent over the 5-year period in Table 2. Projecting these percentages on our estimated range of administrative detention actions that will be contested gives up to 1.9 (= 2 contested administrative detentions * 95 percent) appeals of administrative detention preceding a voluntary class I recalls and up to 0.1 (= 2 contested administrative detentions * 5 percent) appeals of administrative detention preceding a seizure.

We estimate the cost of appealing an administrative detention order issued prior to a voluntary class I recall to be between $0 (= 0 administrative detentions per year * $61,000 per appeal) and $164,350 (= 1.9 administrative detentions per year * $86,500 per appeal). We estimate the cost of appealing an administrative detention order issued prior to a seizure to be between $0 (= 0 administrative detentions per year * $35,500 per appeal) and $7,430 (= 0.1 administrative detentions per year * $74,300 per appeal). Therefore, the cost to FDA of the appeals process of a detained shipment is estimated to range, on average, from $0 (= $0 for class I recall + $0 for seizure) to $171,780 (=$164,350 for class I recall + $7,430 for seizure) per year.

3. Costs of Preparing for an Appeal of an Administrative Detention

In addition to preparing for, participating in, and conducting a contested administrative detention action, FDA will also incur costs every time an administrative detention is ordered in order to prepare for a possible appeal, given the statutory requirement that within five days of the date an appeal is filed, FDA must after affording opportunity for an informal hearing by order confirm the detention or revoke it. We estimate FDA will incur costs to prepare for an appeal up to 25 percent of the cost to prepare for, participate in, and conduct an appeal of an administrative detention. As a result, we anticipate costs to FDA in the range of $15,250 (= $61,000 per appeal * 25 percent) to $21,625 (= $86,500 * 25 percent) just to prepare for an appeal of an administrative detention.

We assume 90 percent of administrative detentions will not be appealed. Therefore, we estimate the costs of preparation for each administrative detention to be between $0 (= 0 administrative detentions * $15,250 per administrative detention appeal preparation) and $389,250 (= 18 administrative detentions * $21,625 per administrative detention appeal preparation).

4. Other Possible Enforcement or Regulatory Costs

Differences in other enforcement or regulatory costs associated with administrative detention actions, class I recalls, and moving directly to seizure actions will also be relevant to this analysis. These costs include the cost of preparing for the action, the record keeping costs by firms of such actions, and the potential loss in value of non-violative products in the same shipment with a detained drug. We do not include the costs of preparing for the action because we assume the activity costs of implementing an administrative detention, requesting a voluntary recall, and moving to directly seize a drug are similar. Likewise, we do not anticipate there being a burden for keeping records of administrative detention actions in addition to recordkeeping requirements as part of current good manufacturing practice. Finally, we will expect market forces to minimize loss of value to non-violative products in the same shipment with a detained product once they are separated from the violative drugs and allowed into commerce because investigating and resealing a load will have little effect on the underlying value of that load.

Administrative detention actions might also cause drugs or other products that we do not administratively detain to lose value if delivery of these products to their final destination were delayed as a result of being packed together with drugs that we did detain. We have not included the potential loss of value from this source because, based on our experience with other administrative detentions, we expect that we will not cause significant delays in the delivery of products that are packed with drugs that we administratively detain.

5. Costs Associated with Administratively Detaining a Non-violative Drug

In the analysis thus far, we have only considered costs for products that FDA rightfully has reason to believe are adulterated or misbranded. This approach was used based on FDA's experience to date with its administrative detention authority for other products. Additional costs to industry and consumers will be incurred if we administratively detain a product that is later determined to be non-violative. If these drugs are later found to not be adulterated or misbranded, several costs, such as those relating to transportation, storage, loss of market value, label removal, and the firm's cost to appeal a detention, will be included as they add to the burden of selling or purchasing a non-violative drug.

6. Summary of Total Costs

Table 3 presents a summary of the estimated total costs that will result with the implementation of the final rule. FDA estimates that implementing the final rule will result in average annual costs ranging from $0 to $602,602. These costs represent a best estimate given the information available. In all cases, we based the low end of the range on the fact that we do not know if we will have used administrative detention, even if we had the authority to do so, and the criteria for using administrative detention had been met. The upper end is based on our limited use of administrative detention with other FDA-regulated products.

Table 3: Summary of Total Costs

	Annual Costs	
	Low Estimate	**High Estimate**
Cost of Marking and Labeling Administratively Detained Drugs	**$0**	**$41,572**
Cost of Appealing an Administrative Detention	**$0**	**$171,780**
Cost of Preparing for an Appeal of an Administrative Detention	**$0**	**$389,250**
Total Social Costs	**$0**	**$602,602**

Additional uncertainties are associated with these cost estimates, but are not reflected in the ranges reported in Table 3. As discussed in the body of this document, differences in the costs of preparing for, participating in, and conducting administrative detention appeals, voluntary class I recalls, and seizures will increase or decrease costs of the final rule. Also, detaining drugs and then releasing them into commerce because they are found to be non-violative will increase the costs associated with administrative detention.

III. Final Regulatory Flexibility Analysis

FDA has examined the economic implications of the final rule as required by the Regulatory Flexibility Act. If a rule will have a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that will lessen the economic effect of the rule on small entities. In the final rule, small entities will bear costs to the extent that they are responsible for the violative drug. The number of expected detentions per year along with the very small value per event implies that this burden would not be significant, so we presume that this final rule will not have a significant economic impact on a substantial number of small entities. This analysis, together with other relevant sections of this document, serves as the Final Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act.

IV. References

1. U.S. Office of Personnel Management, "2012 General Schedule (GS) Locality Pay Tables – 2012 General Schedule (Base), Hourly Rate" available at http://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2012/general-schedule/gs_h.pdf.