Johnson & Johnson Consumer Inc.

CARES Act

Drug Amount Reporting

OTC Products

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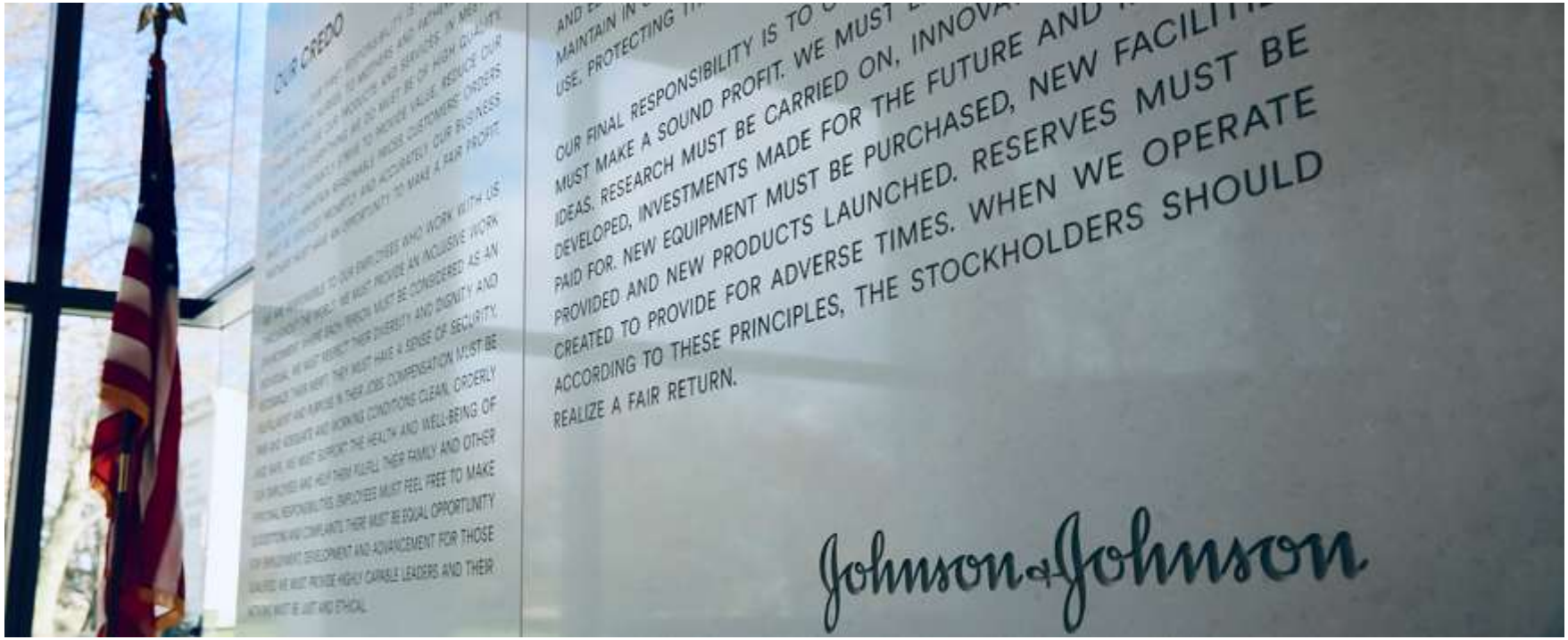

At Johnson & Johnson, we are committed to providing safe, innovative and life-enhancing products that meet or exceed customer and regulatory requirements through a culture of customer focus, continuous improvement, collaboration, and excellence in all that we do.

The values that guide our decision-making are spelled out in Our Credo. Put simply, Our Credo challenges us to put the needs and well-being of the people we serve first.

CARES Drug Amount Reporting OTC

Topics:

Road Map Adventure
Workload, Data Source and Resources
Responsibilities
Learnings
Recommendations

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Road map adventure

Oct 2021

FDA post the guidance

Gather and Share

Cross-company and sector.

Develop

Develop a process to obtain the data.

Analysis and Reporting

While executing refining the process

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Workload

NDC Reported
- Nine Labeler Codes
- 2021 (930 NDCS)

Lines of Data submitted
- 16,029 (2021)

Reports Submitted
- 9 (2021)
- Note: 21 reports for 2020

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Data sources

- ✓ FDA National Drug Code Directory.

NDC database file - Excel version (zip format)
https://www.accessdata.fda.gov/cder/ndcxls.zip

- ✓ SAP Report
- ✓ NDC List
- ✓ Specifications
- ✓ Drug Establishments Current Registration Site
- ✓ CDER/Direct- Drug Listings

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Resources

SAP Report (1 resource)

- Development -Approximately 2 weeks.
- Questions/Clarifications – 6-8 hrs.
- Report Generation -2-4hrs (every time that is needed).

Analysis and Final Reporting

- 2.5 dedicated resources for 3 months

Responsibility interpretation

Reporting Amount of Listed Drugs and Biological Products Under 1 **Section 510(j)(3) of the FD&C Act** 2 **Guidance for Industry1**

III A. Content of Reports

Each registrant that lists a drug must report to FDA annually on the amount of such drug that it manufactured, prepared, propagated, compounded, or processed (including repacking and relabeling[12]) for commercial distribution.[13]

The report should provide the amount of each listed drug, identified by National Drug Code (NDC), that was released by each registered establishment during the reported year, organized by the amount of drug released in each month.[14] Repackers and relabelers should also include in their reports the source NDC (i.e., the full three-segment NDC assigned to the drug received by the repacker/relabeler for repacking or relabeling), if available.

Responsibility interpretation

Reporting Amount of Listed Drugs and Biological Products Under 1 **Section 510(j)(3) of the FD&C Act** 2 **Guidance for Industry1**

III A. Content of Reports

Registrants should also report the single business operation that is most relevant to the overall business operations performed for the listed drug at the registered establishment in that year.[15] The business operation information provided in the section 510(j)(3) report may be different from the business operation(s) included in the drug listing because the drug listing file may identify multiple business operations, whereas the 510(j)(3) report should identify a single business operation.

Learnings

Identify Active NDCs for the 2020 report.

- Number of NDC listed in a year varies from the previous year depending on delisting and new listing.

Lessons Learned:

On Dec 31- save a report from National Drug Code Directory.

NDC database file - Excel version (zip format)

https://www.accessdata.fda.gov/cder/ndcxls.zip

Learnings

Compiling and Evaluating Data

1. Compiling data for FDA CARES Act required matching both SAP data and listed NDC with a common connecting link- product code.

2. Establishment that releases the material code needs to be traced up to the manufacturing establishment. (Note: exceptions repack/relabel)

Learnings

Compiling and Evaluating Data

3. Ensure Repack was adequately understood per definition, not the common business use.

[13]For purposes of selecting the appropriate business operation, *repackaging* involves removing the drug from the container in which it was received by the establishment and placing the drug into a different container without manipulating, changing, or affecting the composition or formulation of the drug(see 21 CFR 207.1).

4. Ensure SAP release data to be reported as *Innermost/Outermost Quantity Released* aligned with the packaging configuration per NDC.

OTC products in Kits (gift sets)

During the CARES Drug Amount Reporting

Individual OTC (NDC-X) released at Manufacture Establishment was reported.

Kit (NDC-Y) released at the Pack Establishment, was traceback to the Manufacture Establishment of the OTC product.

No mechanism to ensure that the “Pack” kit/gift set and the individual product are linked may result in double counting.

Recommendation

Registrants are required to report "on the amount" of listed drugs manufactured, prepared, propagated, compounded, or processed for commercial distribution.[54] If such amount for an individual registrant is zero, the registrant still must submit a report under section 510(j)(3) of the FD&C Act.

.**Recommendation (1):**

If the product contains multiple manufacturing establishments, however, only one site manufactured and the product was released, we should only report that establishment.

Only report Zero if there is no release at all for that product.

Recommendation

III A. Content of Reports

The report should provide the amount of each listed drug, identified by National Drug Code (NDC), that was released by each registered establishment during the reported year, organized by the amount of drug released in each month.

Recommendation (2):

- To provide the released information for the year, not per month.

- Include this as part of the Annual Product Review process or Part of the Blanket no changes certification of Product Listing process.

Recommendation

III A. Content of Reports

Registrants should also report the single business operation that is most relevant to the overall business operations performed for the listed drug at the registered establishment in that year.[15]

Recommendation (3):

Clarification should be added to the guidance on the “Most relevant” business operation.

Recommendation

III B. Timing Report

Reports for subsequent calendar years should be submitted no later than February 15 of the following calendar year.

Recommendation (4):

In order to collect, evaluate, and generate the report.

The Report day should be moved from 15Feb to at least **15Apr** annually.

Recommendation

Over the Counter medicines (OTCs) generally have a different Benefit / Risk profile and are intended for symptomatic relief for minor conditions that can be self-diagnosed.

The administrative burden incurred by reporting volumes of **all OTCs** substantially outweighs the public health benefit of potentially mitigating shortages of OTCs.

This is especially true considering most OTCs are produced by multiple manufacturers with diverse supply chains.

We encourage the FDA to **only require annual reporting of volumes of OTCs that appear on the FDA's Essential Medicines List** which have been determined to be medically necessary in times of public health emergencies.

Summary

Road Map Adventure
Workload, Data Source and Resources
Responsibilities
Learnings including Pack Kit/Gift set
Recommendations

- Zero reporting- Only report Zero if there is no release at all for that product
- Provide the released information for the year, not per month. And include this as part of the Annual Product Review process or Part of the Blanket no changes certification of Product Listing process.
- Clarification on the “Most relevant” business operation.
- Change the Report day to 15Apr annually.
- Only require annual reporting of volumes of OTCs that appear on the FDA’s Essential Medicines List.


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謝謝
ngiyabonga
teşekkür ederim
спасибо
dank je
thank you
gracias
mauruuru
hvala
mochchakkeram
dziękuje
go raibh maith agat
obrigado
sukriya
kop
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