

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN <sup>1</sup>

| Activity   | Number of respondents | Number of disclosures per respondent | Total annual disclosures | Average burden per disclosure | Total hours | Total capital costs |
|--|-----------------------|--------------------------------------|--------------------------|-------------------------------|-------------|---------------------|
| Review labels to follow guidance recommendations .....   | 77,500                | 1                                    | 77,500                   | 1                             | 77,500      | 0                   |
| Redesign labels to follow guidance recommendations ..... | 775                   | 1                                    | 775                      | 16                            | 12,400      | \$1,414,375         |
| Total .....  |                       |                                      |                          |                               | 89,900      | 1,414,375           |

<sup>1</sup> There are no operating and maintenance costs associated with this collection of information.

We base these estimates from our experience with our food allergen labeling program and our labeling cost model. We estimate that there are approximately 775,000 Universal Product Codes (UPCs) of FDA-regulated foods. Using FDA’s labeling cost model, we estimate the entry rate of new UPCs to be approximately 8 percent per year. Based on the approximate entry rate of new UPCs, we estimate the rate of new or reformulated UPCs to be approximately 10 percent per year, or 77,500 products (775,000 ×10 percent). Thus, we estimate that 77,500 new or reformulated products are sold annually in the United States. Assuming an association of 1 respondent to each of the 77,500 new or reformulated products, we estimate that 77,500 respondents will each review the label of one of the 77,500 new or reformulated products, as reported in table 1, row 1. We have no data on how many label reviews would identify an opportunity to redesign the label. Therefore, we further estimate, for the purposes of this analysis, that 1 percent of the reviewed labels of new or reformulated products, or 775 labels (77,500 × 1 percent) would be redesigned as recommended by the guidance. Assuming an association of 1 respondent to each of the 775 labels, we estimate that 775 respondents will each redesign 1 label. Using our labeling cost model, we estimate that it will take an average of 16 hours to complete the administration and internal design work

for the redesign of a label to follow the recommendations of the guidance, as reported in table 1, row 2. Consequently, the burden of redesigning the 775 labels of new or reformulated products is 12,400 hours, as reported in table 1, row 2.

**III. Electronic Access**

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/FoodGuidances> or <https://www.regulations.gov>. Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: November 2, 2020.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

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**BILLING CODE 4164–01–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket Nos. FDA–2019–N–3065; FDA–2016–N–4620; FDA–2019–N–6063; FDA–2017–N–1066; FDA–2018–N–3065; FDA–2008–N–0424; and FDA–2019–N–5711]

**Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at <https://www.reginfo.gov/public/do/PRAMain>. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

| Title of collection   | OMB control No. | Date approval expires |
|---|-----------------|-----------------------|
| Required Warnings for Cigarette Packages and Advertisements .....                                     | 0910–0877       | 04/30/2023            |
| Medical Devices; Reports of Corrections and Removals .....  | 0910–0359       | 10/31/2023            |
| Customer/Partner Service Surveys .....  | 0910–0360       | 10/31/2023            |
| Annual Reporting for Custom Device Exemption .....  | 0910–0767       | 10/31/2023            |
| Human Drug Compounding Under Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act ..... | 0910–0800       | 10/31/2023            |
| Postmarketing Safety Reporting for Combination Products .....   | 0910–0834       | 10/31/2023            |
| Importation of Prescription Drugs .....   | 0910–0888       | 10/31/2023            |

Dated: November 5, 2020.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2014-N-0998]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Regulations for In Vivo Radiopharmaceuticals Used for Diagnosis and Monitoring

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the collections of information in the regulations for in vivo radiopharmaceuticals used for diagnosis and monitoring.

**DATES:** Submit either electronic or written comments on the collection of information by January 11, 2021.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before January 11, 2021. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 11, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

#### Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to [https://](https://www.regulations.gov)

[www.regulations.gov](https://www.regulations.gov) will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

**Instructions:** All submissions received must include the Docket No. FDA-2014-N-0998 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Regulations for In Vivo Radiopharmaceuticals Used for Diagnosis and Monitoring." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in

its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

**FOR FURTHER INFORMATION CONTACT:** Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether