been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA).

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrahi, 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.

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the PRA (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>
<thead>
<tr>
<th>Title of collection</th>
<th>OMB control No.</th>
<th>Date approval expires</th>
</tr>
</thead>
<tbody>
<tr>
<td>Applications for FDA Approval to Market a New Drug</td>
<td>0910–0001</td>
<td>3/31/2024</td>
</tr>
<tr>
<td>Medical Devices; Humanitarian Use Devices</td>
<td>0910–0332</td>
<td>3/31/2024</td>
</tr>
<tr>
<td>Medical Devices; Device Tracking</td>
<td>0910–0442</td>
<td>3/31/2024</td>
</tr>
<tr>
<td>Dispute Resolution Procedures for Science Based Decision on Products Regulated by CVM</td>
<td>0910–0566</td>
<td>3/31/2024</td>
</tr>
<tr>
<td>Use of Public Human Genetic Variant Databases to Support Clinical Validity for Genetic and Genomic-Based Medical Devices; Humanitarian Use Devices</td>
<td>0910–0850</td>
<td>3/31/2024</td>
</tr>
<tr>
<td>Assessment of Terms and Phrases Commonly Used in Prescription Drug Promotion</td>
<td>0910–0895</td>
<td>3/31/2024</td>
</tr>
</tbody>
</table>


Lauren K. Roth,
Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–09811 Filed 5–7–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
[Docket Nos. FDA–2021–N–0387]

Agency Information Collection Activities; Proposed Collection; Comment Request; Recommended Content of Medical Product Communications That Are Consistent With the Food and Drug Administration-Required Labeling and Recommendations for Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities

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 information collection associated with recommended content of medical product communications that are consistent with the FDA-required labeling and recommendations for drug and device manufacturer communications with payors, formulary committees, and similar entities.

DATES: Submit either electronic or written comments on the collection of information by July 9, 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 July 9, 2021. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of July 9, 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://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 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–2021–N–0387 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Recommended Content of Medical Product Communications That Are Consistent With the FDA-Required Labeling and Recommendations for Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities.” 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 http://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, PRASTaff@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 the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

I. Medical Product Communications That Are Consistent With the FDA-Required Labeling—Questions and Answers

OMB Control Number 0910–0856—Extension

This information collection supports the Federal Food, Drug, and Cosmetic Act (FD&C Act) and FDA’s implementing regulations that govern drug and device labeling and prescription drug and restricted device advertising. The FD&C Act specifies that a drug or device shall be deemed to be misbranded if its labeling is false or misleading in any particular (section 502(a) [21 U.S.C. 352(a)]) and that labeling may be considered misleading if it fails to reveal material facts about the product being promoted, including facts that are material in light of the representations made in a promotional piece. The FD&C Act also specifies that restricted device advertisements must not be false or misleading (section 502(q)(1)) and must reveal facts that are material about the product being advertised (section 201(n)).

To assist respondents with the requirements drug and device labeling and prescription drug and restricted device advertising, we developed the guidance for industry entitled “Medical Product Communications That Are Consistent With the FDA-Required Labeling—Questions and Answers” (June 2018) (medical product communications guidance), available at https://www.fda.gov/media/133619/download. This medical product communications guidance includes recommendations that firms consider when developing “consistent with the FDA-required labeling (CFL)” presentations in their labeling and advertising materials to help ensure the presentations are not false or misleading in violation of the FD&C Act and FDA’s implementing regulations. The guidance also describes FDA’s thinking when examining the consistency of a firm’s product communications with that product’s own FDA-required labeling.

As explained in the guidance, if a firm communicates information that is not contained in its product’s FDA-required labeling but that is determined to be consistent with the FDA-required labeling, FDA does not intend to rely on that communication to establish a new intended use that is different from the use or uses for which the product is legally marketed. Establishing a product’s intended uses is an element in establishing certain violations under the FD&C Act and Public Health Service Act. Firms’ communications about their products that are consistent with the products’ FDA-required labeling but that are false or misleading may subject a firm to enforcement action under the FD&C Act. Thus, the guidance not only describes FDA’s thinking on communications that are consistent with the FDA-required labeling, but also provides general recommendations intended to help firms comply with requirements in the FD&C Act and FDA’s implementing regulations for conveying information that is consistent with the FDA-required labeling in a truthful and non-misleading way.

The medical product communications guidance recommends that firms accurately represent in the communications any study results or other data and information that are relied upon to support a firm’s CFL promotional communication. Other
recommendations include the clear and prominent disclosure of aspects of study design and methodology that are material for audiences to accurately interpret the information being presented (e.g., type of study, study objectives, product dosage and use regimens, control or controls used, patient population studied), as well as material limitations related to the study design, methodology, and results. Also, the guidance recommends that firms accurately characterize and contextualize the relevant information about the product, including by disclosing unfavorable or inconsistent findings. In addition, the guidance recommends that firms disclose material contextual information from the FDA-required labeling in these communications, such as data and information from studies in the FDA-required labeling that are relevant to the data or information presented in the CFL promotional communication. The recommendations will help ensure that health care professional and consumer audiences receive truthful information about the benefits and risks of drugs and devices in firms’ CFL promotional communications and that material contextual information is included in these communications so that audiences are not misled. Accurate information helps these audiences know whether drugs or devices may be appropriate for them or their patients and know what they can expect to experience when prescribing or using these products.

We estimate the burden of this collection of information as follows:

<table>
<thead>
<tr>
<th>Recommended information to be included when firms choose to disseminate communications that are consistent with the FDA-required labeling</th>
<th>Number of respondents</th>
<th>Number of disclosures per respondent</th>
<th>Total annual disclosures</th>
<th>Average burden per disclosure</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>324 30</td>
<td>9,720</td>
<td>4</td>
<td>38,880</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*There are no capital costs or operating and maintenance costs associated with this collection of information.*
TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN 1

<table>
<thead>
<tr>
<th>Information collection activity</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Total annual responses</th>
<th>Average burden per response</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recommended information to be included when firms choose to disseminate HCEI materials to payors about approved prescription drugs</td>
<td>430</td>
<td>10.465</td>
<td>4,500</td>
<td>20</td>
<td>90,000</td>
</tr>
<tr>
<td>Recommended information to be included when firms choose to disseminate HCEI materials to payors about approved or cleared devices</td>
<td>236</td>
<td>10</td>
<td>2,360</td>
<td>20</td>
<td>47,200</td>
</tr>
<tr>
<td>Recommended information to be included when firms choose to disseminate information about unapproved products or unapproved uses of approved or cleared products</td>
<td>717</td>
<td>2</td>
<td>1,434</td>
<td>0.5</td>
<td>717</td>
</tr>
<tr>
<td>Follow-up information to payors regarding previously communicated information about unapproved products or unapproved uses of approved or cleared products</td>
<td>359</td>
<td>2</td>
<td>718</td>
<td></td>
<td>1,436</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>9,012</strong></td>
<td><strong>2</strong></td>
<td><strong>139,353</strong></td>
<td></td>
<td><strong>139,353</strong></td>
</tr>
</tbody>
</table>

1 There are no capital costs or operating and maintenance costs associated with this collection of information.

We have adjusted the estimate of burden we associate with the information collection recommendations in the guidance to reflect an increase of 2,000 hours and 100 responses annually.


Lauren K. Roth,
Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–09809 Filed 5–7–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0742]

Agency Information Collection Activities; Proposed Collection; Comment Request; Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, we, 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 information collection associated with drug establishment registration and product listing requirements.

DATES: Submit either electronic or written comments on the collection of information by July 9, 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 July 9, 2021. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of July 9, 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://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–2011–N–0742 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution.” 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