scheduled presentation times. Persons registered to speak should check in
before the workshops and are
encouraged to arrive early to ensure
their designated order of presentation.
Participants who are not present when
called may not be permitted to speak at
a later time. An agenda will be made
available at least 3 days before each
workshop at https://www.fda.gov/
Drugs/NewsEvents/ucm582091.htm.
FDA may also post specific questions
for consideration at the meeting Web
page; these will be made available at
least 3 days before each workshop at
https://www.fda.gov/Drugs/NewsEvents/
ucm582091.htm.

Streaming Webcast and Video of the
Public Workshops: These public
workshops will be webcast; the URL
will be posted at https://www.fda.gov/
Drugs/NewsEvents/ucm582091.htm at
least 1 day before each workshop. A
video record of the public workshops
will be available at the same Web site
address for 1 year.

Leslie Kux,
Associate Commissioner for Policy.

[FR Doc. 2017–24918 Filed 11–16–17; 8:45 am]
BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND
HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0878]

Agency Information Collection Activities; Proposed Collection; Comment Request; Premarket Notification for a New Dietary Ingredient

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 procedure by
which a manufacturer or distributor of
a new dietary ingredient or of a dietary
supplement containing a new dietary
ingredient is to submit to FDA
information upon which it has based its
conclusion that a dietary supplement
containing the new dietary ingredient
will reasonably be expected to be safe.

DATES: Submit either electronic or
written comments on the collection of
information by January 16, 2018.

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 16,
electronic filing system will accept
comments until midnight Eastern Time
at the end of January 16, 2018.

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.

• 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–2013–N–0878
for “Premarket Notification for a New Dietary
Ingredient.” 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
available at https://www.regulations.gov
or at the Dockets Management Staff
between 9 a.m. and 4 p.m., Monday
through Friday.

• 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
to comments to public dockets, see 80 FR
56469, September 18, 2015, or access
the information at: https://www.gpo.gov/
fdsys/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.

FOR FURTHER INFORMATION CONTACT: Ila
Mizrachi, Office of Operations, Food
and Drug Administration, Three White
Flint North, 10A–12M, 11601
Landsdown St., North Bethesda, MD
SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), 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, 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, 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.

Premarket Notification for a New Dietary Ingredient—21 CFR 190.6

OMB Control Number 0910–0330—Extension

This information collection supports Agency regulations. Specifically, section 413(a) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 350b[a]) provides that at least 75 days before the introduction or delivery for introduction into interstate commerce of a dietary supplement that contains a new dietary ingredient, the manufacturer or distributor of the dietary supplement or of the new dietary ingredient is to submit to FDA (as delegate for the Secretary of Health and Human Services) information upon which the manufacturer or distributor has based its conclusion that a dietary supplement containing the new dietary ingredient will reasonably be expected to be safe. FDA’s implementing regulation, § 190.6 (21 CFR 190.6), requires this information to be submitted to the Office of Nutrition, Labeling, and Dietary Supplements (ONLDS) in the form of a notification. Under § 190.6(b), the notification must include the following: (1) The name and complete address of the manufacturer or distributor; (2) the name of the new dietary ingredient; (3) a description of the dietary supplement(s) that contain the new dietary ingredient, including the level of the new dietary ingredient in the dietary supplement and the dietary supplement’s conditions of use; (4) the history of use or other evidence of safety establishing that the new dietary ingredient will reasonably be expected to be safe when used under the conditions recommended or suggested in the labeling of the dietary supplement; and (5) the signature of a responsible person designated by the manufacturer or distributor.

These premarket notification requirements are designed to enable us to monitor the introduction into the marketplace of new dietary ingredients and dietary supplements that contain new dietary ingredients in order to protect consumers from ingredients and products whose safety is unknown. FDA uses the information collected in new dietary ingredient notifications to evaluate the safety of new dietary ingredients in dietary supplements and to support regulatory action against ingredients and products that are potentially unsafe.

FDA has developed an electronic portal that respondents may use to electronically submit their notifications to ONLDS via FDA Unified Registration and Listing System (FURLS). Firms that prefer to submit a paper notification in a format of their own choosing still have the option to do so; however, Form FDA 3880 prompts a submitter to input the elements of a new dietary ingredient notification (NDIN) in a standard format and helps the respondent organize its NDIN to focus on the information needed for FDA’s safety review. Safety information may be submitted via a supplemental form entitled “New Dietary Ingredient Safety Information.” This form provides a standard format to describe the history of use or other evidence of safety on which the manufacturer or distributor bases its conclusion that the new dietary ingredient is reasonably expected to be safe under the conditions of use recommended or suggested in the labeling of the dietary supplement, as well as related identity information that is necessary to demonstrate safety by showing that the new dietary ingredient and dietary supplement(s) that are the subject of the notification are the same or similar to the ingredients and products for which safety data and information have been provided. We invite comment on Form FDA 3880 and the supplemental safety information form, which may be found on our Web site at https://www.fda.gov/Food/DietarySupplements/NewDietaryIngredientsNotificationProcess/default.htm.

Description of Respondents: The respondents to this collection of information are manufacturers and distributors in the dietary supplement industry; specifically, firms that manufacture or distribute new dietary ingredients or dietary supplements that contain a new dietary ingredient.

FDA estimates the burden of this collection of information as follows:

<table>
<thead>
<tr>
<th>21 CFR section</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Total annual responses</th>
<th>Average burden per response (in hours)</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>190.6: Dietary Supplements ........................................</td>
<td>55</td>
<td>1</td>
<td>55</td>
<td>20</td>
<td>1,100</td>
</tr>
</tbody>
</table>

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

We have made no adjustments to the currently approved burden estimate for the information collection. While we have received previous comments suggesting our burden estimate may be too low, the comments did not discuss the basis for such a conclusion. We therefore specifically invite those commenters offering an alternative...
burden estimate to include the methodology or reasoning used to do so.

Based on our experience with the information collection over the past 3 years, we estimate that 55 respondents will submit 1 premarket notification each. We estimate that extracting and summarizing the relevant information from what exists in the company’s files and presenting it in a format that meets the requirements of §190.6 will take approximately 20 hours of work per notification. We have carefully considered the burden associated with the premarket notification requirement and believe that estimates greater than 20 hours are likely to include burden associated with researching and generating safety data for a new dietary ingredient. We also believe that the burden of the premarket notification requirement on industry is minimal and reasonable because we are requesting only safety and identity information that the manufacturer or distributor should already have developed to satisfy itself that a dietary supplement containing a new dietary ingredient is in compliance with the FD&C Act. Under section 413(a)(2) of the FD&C Act, a dietary supplement that contains a new dietary ingredient is deemed to be adulterated unless there is a history of use or other evidence of safety establishing that the new dietary ingredient will reasonably be expected to be safe under the conditions of use recommended or suggested in the labeling of the dietary supplement. This requirement is separate from and additional to the requirement to submit a premarket notification for the new dietary ingredient. FDA’s regulation on new dietary ingredient notifications, §190.6(a), requires the manufacturer or distributor of the dietary supplement or of the new dietary ingredient to submit to FDA the information that forms the basis for its conclusion that a dietary supplement containing the new dietary ingredient will reasonably be expected to be safe. Thus, §190.6 only requires the manufacturer or distributor to extract and summarize information that should have already been developed to meet the safety requirement in section 413(a)(2) of the FD&C Act.

Dated: November 9, 2017.

Anna K. Abram,
Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–24925 Filed 11–16–17; 8:45 am]
BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry, Researchers, Patient Groups, and Food and Drug Administration Staff on Meetings With the Office of Orphan Products Development

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 Guidance for Industry, Researchers, Patient Groups, and FDA Staff on Meetings with the Office of Orphan Products Development.

DATES: Submit either electronic or written comments on the collection of information by January 16, 2018.

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 16, 2018. The https://www.regulations.gov electronic filing system will accept comments until midnight Eastern Time at the end of January 16, 2018. 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 in their entirety. 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–D–0313 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry, Researchers, Patient Groups, and Food and Drug Administration Staff on Meetings with the Office of Orphan Products Development.” 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.
• 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 identified by the Agency, will be made available to the public.