§ 60.30, including but not limited to:
Must be timely (see DATES), must be
filed in accordance with § 10.20, must
contain sufficient facts to merit an FDA
investigation, and must certify that a
true and complete copy of the petition
has been served upon the patent
applicant. (See H. Rept. 857, part 1, 98th
Cong., 2d sess., pp. 41–42, 1984.)
Petitions should be in the format
Submit petitions electronically to
https://www.regulations.gov at Docket
No. FDA–2013–S–0610. Submit written
petitions (two copies are required) to the
Dockets Management Staff (HFA–305),
Food and Drug Administration, 5630
Fishers Lane, Rm. 1061, Rockville, MD
20852.
Leslie Kux,
Associate Commissioner for Policy.
[FR Doc. 2016–01373 Filed 1–25–16; 8:45 am]
BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND
HUMAN SERVICES
Food and Drug Administration
[Docket No. FDA–2018–N–0073]
Agency Information Collection
Activities; Proposed Collection;
Comment Request; Irradiation in the
Production, Processing, and Handling of
Food
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 provisions of our
requirements for food irradiation
processors.
DATES: Submit either electronic or
written comments on the collection of
information by March 27, 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 March 27,
electronic filing system will accept
comments until midnight Eastern Time
at the end of March 27, 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 unchanged. Because your
comment will be made public, you are
soley 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
detailed as in “Instructions.”
Instructions: All submissions received
must include the Docket No. FDA–
2018–N–0073 for “Agency Information
Collection Activities; Proposed
Collection; Comment Request;
Irradiation in the Production,
Processing, and Handling of Food.”
Received comments, those filed in a
timely manner (see ADDRESS) 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
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 docket, see 80
FR 56469, September 18, 2015, or access
the information at: https://www.gpo.gov/
fsys/pkg/FR-2015-09-18/pdf/2015-
23869.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:
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. 3501–3520), 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, 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.

Irradiation in the Production, Processing, and Handling of Food
OMB Control Number 0910–0186—Extension

This information collection supports FDA regulations. Specifically, under sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 321(s) and 348), food irradiation is subject to regulation under the food additive premarket approval provisions of the FD&C Act. The regulations providing for uses of irradiation in the production, processing, and handling of food are found in part 179 (21 CFR part 179). To ensure safe use of a radiation source, §179.21(b)(1) requires that the label of sources bear appropriate and accurate information identifying the source of radiation and the maximum (or minimum and maximum) energy of the emitted radiation. Section 179.21(b)(2) requires that the label or accompanying labeling bear adequate directions for installation and use and a statement supplied by us that indicates maximum dose of radiation allowed. Section 179.26(c) requires that the label and accompanying labeling bear a logo and a radiation disclosure statement. Section 179.25(e) requires that food processors who treat food with radiation make and retain, for 1 year past the expected shelf life of the products up to a maximum of 3 years, specified records relating to the irradiation process (e.g., the food treated, lot identification, scheduled process, etc.). The records required by §179.25(e) are used by our inspectors to assess compliance with the regulation that establishes limits within which radiation may be safely used to treat food. We cannot ensure safe use without a method to assess compliance with the dose limits, and there are no practicable methods for analyzing most foods to determine whether they have been treated with ionizing radiation and are within the limitations set forth in part 179. Records inspection is the only way to determine whether firms are complying with the regulations for treatment of foods with ionizing radiation.

Description of respondents: Respondents to the information collection are businesses engaged in the irradiation of food.

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

<table>
<thead>
<tr>
<th>21 CFR section</th>
<th>Number of recordkeepers</th>
<th>Number of records per recordkeeper</th>
<th>Total annual records</th>
<th>Average burden per recordkeeping</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>179.25(e), large processors</td>
<td>4</td>
<td>300</td>
<td>1,200</td>
<td>1</td>
<td>1,200</td>
</tr>
<tr>
<td>179.25(e), small processors</td>
<td>4</td>
<td>30</td>
<td>120</td>
<td>1</td>
<td>120</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1,320</td>
</tr>
</tbody>
</table>

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

Upon review of the information collection we have retained the currently approved burden estimate. Our estimate of the recordkeeping burden under §179.25(e) is based on our experience regulating the safe use of radiation as a direct food additive. The number of firms who process food using irradiation is extremely limited. We estimate that there are four irradiation plants whose business is devoted primarily (i.e., approximately 100 percent) to irradiation of food and other agricultural products. Four other firms also irradiate small quantities of food. We estimate that this irradiation accounts for no more than 10 percent of the business for each of these firms. Therefore, the average estimated burden is based on four facilities devoting 10 percent of their business to food irradiation (4 × 300 hours = 1,200 hours for recordkeeping annually), and four facilities devoting 10 percent of their business to food irradiation (4 × 30 hours = 120 hours for recordkeeping annually).

No burden has been estimated for the labeling requirements in §§179.21(b)(1), 179.21(b)(2), and 179.26(c) because the disclosures are supplied by FDA. Under 5 CFR 1320.3(c)(2), the public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public is not subject to review by the OMB under the PRA.


Leslie Kux,
Associate Commissioner for Policy.

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
[Docket No. FDA–2017–D–6878]

Hypertension: Developing Fixed-Dose Combination Drugs for Treatment; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled “Hypertension: Developing Fixed-Dose Combination Drugs for Treatment.” The purpose of this guidance is to assist sponsors in the clinical development of