veterinary and human drug products and human biological drug products.

FDA estimates that approximately two manufacturers will submit approximately two requests annually for a tier-one DR and that there will be one appeal of these requests to the DR Panel (request for tier-two DR). FDA estimates that it will take manufacturers approximately 30 hours to prepare and submit each request for a tier-one DR and approximately 8 hours to prepare and submit each request for a tier-two DR. Table 1 provides an estimate of the annual reporting burden for requests for tier-one and tier-two DRs.

In the **Federal Register** of August 11, 2014 (79 FR 46836), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Requests for Tier-One DR	2	1	2	30	60
Requests for Tier-Two DR	1	1	1	8	8
Total					68

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

Dated: December 17, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–29917 Filed 12–22–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1104]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; State Petitions for Exemption From Preemption

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''State Petitions for Exemption from Preemption'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On October 27, 2014, the Agency submitted a proposed collection of information entitled ''State Petitions for Exemption from Preemption'' to OMB for review and clearance under 44 U.S.C. 3507. 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. OMB has now approved the information collection and has assigned OMB control number 0910–0277. The approval expires on November 30, 2017. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: December 17, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–30012 Filed 12–22–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0588]

Compliance Policy Guide Sec. 540.700 Labeling of Processed and Blended Seafood Products Made Primarily With Fish Protein; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of Compliance Policy Guide Sec. 540.700 Labeling of Processed and Blended Seafood Products Made Primarily with Fish Protein (the CPG). The CPG provides guidance for our staff on our labeling requirements for processed and blended seafood products made primarily with fish protein.

DATES: Submit either electronic or written comments on FDA's CPGs at any time.

ADDRESSES: Submit written requests for single copies of the CPG to the Office of Policy and Risk Management, Office of Regulatory Affairs, Office of Global Regulatory Operations and Policy, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the CPG.

Submit electronic comments on the CPG to *http://www.regulations.gov.* Submit written comments on the CPG to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Catalina Ferre-Hockensmith, Center for Food Safety and Applied Nutrition (HFC–820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–2371.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of revised Compliance Policy Guide Sec. 540.700 Labeling of Processed and Blended Seafood Products Made Primarily with Fish Protein. We are issuing the revisions to the CPG as Level 2 guidance under our good guidance practices regulation (21 CFR 10.115). Consistent with our good guidance practices regulation, we will accept comments on the CPG at any time. The CPG represents our current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

The CPG updates previously issued CPG Sec. 540.700 Processed and/or

Blended Seafood Products, which provides guidance for our staff on labeling requirements for processed and blended seafood products made primarily with fish protein. The CPG has been revised for clarity and format, including the addition of Regulatory Action Guidance and Specimen Charges sections. The CPG contains information that may be useful to the regulated industry and to the public.

II. Comments

Interested persons may submit either written comments regarding the guidance to the Division of Dockets Management (see **ADDRESSES**) or electronic comments regarding the guidance to *http://www.regulations.gov.* It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

III. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/default.htm* or *http://www.regulations.gov.* Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

Dated: December 18, 2014.

Melinda K. Plaisir,

Associate Commissioner for Regulatory Affairs, Office of Regulatory Affairs.

[FR Doc. 2014–30015 Filed 12–22–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–1696]

Minimal Manipulation of Human Cells, Tissues, and Cellular- and Tissue-Based Products; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Minimal Manipulation of Human Cells, Tissues, and Cellular- and Tissue-Based Products; Draft Guidance for Industry and Food and Drug Administration Staff.'' The draft guidance document provides human cells, tissues, and cellular- and tissue-based product (HCT/P) manufacturers, healthcare providers, and FDA staff with recommendations for meeting the criterion of ''minimal manipulation'' as it applies to HCT/Ps. The draft guidance, when finalized, is intended to supersede the document entitled ''Guidance for Industry and FDA Staff: Minimal Manipulation of Structural Tissue Jurisdictional Update'' dated September 2006. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by February 23, 2015.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002, or to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002, or you may send an email request to the Office of Combination Products (OCP) at *combination@fda.gov.* If you are submitting a written request, send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–7800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Melissa Segal, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911, or Angela Krueger, Office of Device Evaluation, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1666, Silver Spring, MD 20993–0002, 301–796–6380, or Leigh Hayes, Office of Combination Products, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Hub 5129, Silver Spring, MD 20993–0002, 301–796–8938.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Minimal Manipulation of Human Cells, Tissues, and Cellular- and Tissue-Based Products; Draft Guidance for Industry and Food and Drug Administration Staff.'' The draft guidance document provides HCT/P manufacturers, healthcare providers, and FDA staff with recommendations for meeting the 21 CFR 1271.10(a)(1) criterion of minimal manipulation. The draft guidance, when finalized, is intended to supersede the document entitled ''Guidance for Industry and FDA Staff: Minimal Manipulation of Structural Tissue Jurisdictional Update'' dated September 2006. Note that FDA intends to publish a separate draft guidance document on the criterion described in § 1271.10(a)(2), the HCT/P is intended for homologous use only as reflected by the labeling, advertising, or other indications of the manufacturer's objective intent.

HCT/Ps are defined in § 1271.3(d) as articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient. FDA has implemented a risk-based approach to the regulation of HCT/Ps. Under the authority of section 361 of the Public Health Service (PHS) Act (42 U.S.C. 264), FDA established regulations for all HCT/Ps to prevent the introduction, transmission, and spread of communicable diseases. These regulations can be found in part 1271. HCT/Ps are regulated solely under section 361 of the PHS Act and part 1271, if they meet all of the following criteria (21 CFR 1271.10(a)):

- The HCT/P is minimally manipulated;
- The HCT/P is intended for homologous use only, as reflected by the labeling, advertising, or other indications of the manufacturer's objective intent;
- The manufacture of the HCT/P does not involve the combination of the cells or tissues with another article, except for water, crystalloids, or a sterilizing, preserving, or storage agent, provided that the addition of water, crystalloids, or the sterilizing, preserving, or storage