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