Submit written requests for single copies of the report to the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the document.

FOR FURTHER INFORMATION CONTACT: Linda M. Wilmot, Center for Veterinary Medicine (HFV–120), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0829, *linda.wilmot@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 9, 2014 (79 FR 53431), CVM announced that it was beginning to explore possible changes to the current review processes for NADAs for the use of multiple new animal drugs in combination drug medicated feeds. In the same **Federal Register** notice, FDA announced the opening of a docket to receive input from the public on this issue. This effort is consistent with the stated performance goal in the Animal Drug User Fee Amendments of 2013 (ADUFA III) goals letter.

In the **Federal Register** of April 29, 2016 (81 FR 25677), FDA published a notice of availability of a draft CVM report, giving interested persons until July 29, 2016, to comment. Those comments were considered as the CVM working group report was finalized without substantive changes. This report was developed for the discussions with the regulated industry for reauthorization of ADUFA.

Persons with access to the Internet may obtain this document on the CVM ADUFA Meetings Web page: *http://www.fda.gov/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/ucm042891.htm.*

Dated: November 15, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–27942 Filed 11–18–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1147]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by December 21, 2016.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0541. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition—OMB Control Number 0910–0541—Extension

As an integral part of its decision making process, we are obligated under the National Environmental Policy Act of 1969 (NEPA) to consider the environmental impact of our actions, including allowing notifications for food contact substances to become effective and approving food additive petitions, color additive petitions, GRAS affirmation petitions, requests for exemption from regulation as a food additive, and actions on certain food labeling citizen petitions, nutrient content claims petitions, and health claims petitions. In 1997, we amended our regulations in part 25 (21 CFR part 25) to provide for categorical exclusions for additional classes of actions that do not individually or cumulatively have a significant effect on the human environment (62 FR 40570, July 29, 1997). As a result of that rulemaking, we no longer routinely require submission of information about the manufacturing and production of our regulated articles. We also have eliminated the previously required Environmental Assessment (EA) and abbreviated EA formats from the amended regulations. Instead, we have provided guidance that contains sample formats to help industry submit a claim of categorical exclusion or an EA to the Center for Food Safety and Applied Nutrition (CFSAN). The guidance document entitled ''Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition'' identifies, interprets, and clarifies existing requirements imposed by statute and regulation, consistent with the Council on Environmental Quality regulations (40 CFR 1507.3). It consists of recommendations that do not themselves create requirements; rather, they are explanatory guidance for our own procedures in order to ensure full compliance with the purposes and provisions of NEPA.

The guidance provides information to assist in the preparation of claims of categorical exclusion and EAs for submission to CFSAN. The following questions are covered in this guidance: (1) What types of industry-initiated actions are subject to a claim of categorical exclusion? (2) What must a claim of categorical exclusion include by regulation? (3) What is an EA? (4) When is an EA required by regulation and what format should be used? (5) What are extraordinary circumstances? and (6) What suggestions does CFSAN have for preparing an EA? Although CFSAN encourages industry to use the EA formats described in the guidance because standardized documentation submitted by industry increases the efficiency of the review process, alternative approaches may be used if these approaches satisfy the requirements of the applicable statutes and regulations. We are requesting the extension of OMB approval for the

information collection provisions in the guidance.

Description of Respondents: The likely respondents include businesses engaged in the manufacture or sale of food, food ingredients, and substances used in materials that come into contact with food.

In the **Federal Register** of August 25, 2016 (81 FR 58517), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
25.15 (a) & (d) (to cover CEs under 25.32(i))	47	1	47	8	376
25.15 (a) &(d) (to cover CEs under 25.32(o))	1	1	1	8	8
25.15 (a) &(d) (to cover CEs under 25.32(q))	3	1	3	8	24
25.40 (a) & (c) EAs	57	1	57	180	10,260
Total					10,668

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

The estimates for respondents and numbers of responses are based on the annualized numbers of petitions and notifications qualifying for categorical exclusions listed under § 25.32(i) and (q) that the Agency has received in the past 3 years. Please note that, in the past 3 years, there have been no submissions that requested an action that would have been subject to the categorical exclusion in § 25.32(o). To avoid counting this burden as zero, we have estimated the burden for this categorical exclusion at one respondent making one submission a year for a total of one annual submission. The burden for submitting a categorical exclusion is captured under § 25.15(a) and (d).

To calculate the estimate for the hours per response values, we assumed that the information requested in this guidance for each of these three categorical exclusions is readily available to the submitter. For the information requested for the exclusion in § 25.32(i), we expect that submitter will need to gather information from appropriate persons in the submitter's company and prepare this information for attachment to the claim for categorical exclusion. We believe that this effort should take no longer than 8 hours per submission. For the information requested for the categorical exclusions in § 25.32(o) and (q), the submitters will almost always merely need to copy existing documentation and attach it to the claim for categorical exclusion. We believe that collecting this information should also take no longer than 8 hours per submission.

For the information requested for the environmental assessments in § 25.40(a) and (c), we believe that submitters will submit an average of 57 environmental assessments annually. We estimate that each submitter will prepare an EA within 3 weeks (120 hours) and revise the EA based on Agency comments (between 40 to 60 hours), for a total preparation time of 180 hours. The burden relating to this collection has been previously approved under OMB control number 0910–0322, ''Environmental Impact Consideration—21 CFR part 25''. Upon approval of this collection of information by OMB, FDA will revise OMB control number 0910–0322 to remove the annual reporting burden for categorical exclusions and environmental assessment requests related to food additive petitions, color additive petitions, requests for exemption from regulation as a food additive, and submission of a food contact notification for a food contact substance. The future burden for categorical exclusion or environmental assessments for these requests will be captured under OMB control number 0910–0541, this collection of information.

Dated: November 15, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–27943 Filed 11–18–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Privacy Act of 1974; System of Records Notice

AGENCY: Department of Health and Human Services (HHS), Office of the Secretary (OS)

ACTION: Notice to establish a new system of records, and to delete related systems.

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, as amended, HHS is establishing a new, department-wide system of records, System No. 09–90–1601 ''Outside Experts Recruited for Non-FACA Activities,'' and deleting four related systems of records that are obsolete or that will be rendered duplicative by the new system. The new system will cover recruitment and other administrative records about individuals outside the HHS workforce who serve or are considered for service on HHS mission-related committees and other assignments requiring specific outside expertise or experience (excluding those that are subject to the Federal Advisory Committee Act (FACA), which are covered under System No. 09–90–0059). The new department-wide System No. 09–90–1601 and the related system deletions are more fully explained in the **SUPPLEMENTARY INFORMATION** section of this Notice.

DATES: The new system of records established in this Notice is effective upon publication, with the exception of the routine uses. The routine uses will be effective 30 days after publication of this Notice, unless comments are received that warrant a revision to this Notice. Written comments on the Notice should be submitted within 30 days. The deletion of System Numbers 09–20–0168, 09–30–0049, 09–37–0022, and 09–90–0080 will be effective 30 days after publication of this Notice.

ADDRESSES: The public should address written comments to: Beth Kramer, HHS Privacy Act Officer, FOIA/PA Division, Hubert H. Humphrey Building—Suite 729H, 200 Independence Avenue SW., Washington, DC 20201, *beth.kramer@hhs.gov.*

FOR FURTHER INFORMATION CONTACT: Beth Kramer, HHS Privacy Act Officer, FOIA/PA Division, Hubert H. Humphrey Building—Suite 729H, 200 Independence Avenue SW.,