4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0099]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Revision of the Requirements for Constituent Materials

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 [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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 0910-0666. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-7726, Ila.Mizrachi@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.

Revision of the Requirements for Constituent Materials--(OMB Control Number 0910-0666)--Extension

In the Federal Register of April 13, 2011 (76 FR 20513), FDA issued a final rule amending the regulation for the use of constituent materials in licensed biological products. Under 21 CFR 610.15(d), the Director of the Center for Biologics Evaluation and Research (CBER) or the Director of the Center for Drugs Evaluation and Research (CDER) may approve, as appropriate, a manufacturer's request for exceptions or alternatives to the regulation for constituent materials. Thus, the provision provides manufacturers of biological products with flexibility, as appropriate, to employ advances in science and technology as they become available, without diminishing public health protections. Manufacturers seeking approval of an exception or alternative must submit a request in writing. The request must be clearly identified with a brief statement describing the basis for the request and the supporting data. The request may be submitted as part of the original biologics application, as an amendment to the original, pending application or as a prior approval supplement to an approved application. The information to be collected assists FDA in identifying and reviewing requests for an exception or alternative to the requirements for constituent materials.

Respondents to this information collection provision are manufacturers of biological products. Since implementation of the final rule, FDA has received no submissions of requests for an exception or alternative for constituent materials. Therefore, FDA is estimating one respondent and annual response annually to account for a possible submission to CBER or

CDER of a request for an exception or alternative for constituent materials. The average burden per response is based on FDA experience with similar information collection requirements.

In the Federal Register of November 29, 2012 (77 FR 71193), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

Table 1.--Estimated Annual Reporting Burden[1]

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
610.15	1	1	1	1	1

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

Dated: May 30, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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