Revision of the Requirements for Constituent Materials

0910-0666

SUPPORTING STATEMENT

Terms of Clearance: None

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Food and Drug Administration (FDA) is requesting an extension of Office of Management and Budget (OMB) Control No. 0910-0666, and OMB approval of the information collection provision listed below:

21 CFR 610.15(d)	Reporting	The Director of the Center for Biologics Evaluation and Research (CBER) or the Director of the Center for Drug Evaluation and Research (CDER) may, as appropriate, approve an exemption or alternative to any requirement in § 610.15, Constituent Materials. Requests for such exceptions must be in writing.

In the Federal Register of April 13, 2011 (76 FR 20513), FDA issued a final rule amending the regulations for the use of constituent materials in licensed biological products under § 610.15 (21 CFR 610.15). This 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. An exception or alternative will be considered for approval when the data submitted in support of such a request establish the safety, purity, and potency of the biological product for the conditions for which the applicant is seeking approval.

FDA issued this regulation under the biological products provisions of the Public Health Service Act (42 U.S.C. 262 and 264) and the drugs and general administrative provisions of the Federal Food, Drug, and Cosmetic Act (sections 201, 301, 501, 502, 503, 505, 510, 701, and 704) (21 U.S.C. 321, 331, 351, 352, 353, 355, 360, 371, and 374). Under these provisions of the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act, FDA has the authority to issue and enforce regulations designed to ensure that biological products are safe, pure, and potent, and prevent the introduction, transmission, and spread of communicable diseases.

2. Purpose and Use of the Information Collection

Manufacturers of biological products seeking approval of an exception or alternative to the requirements for constituent materials 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 license application, as an amendment to the original, pending application, or as a prior approval supplement to an approved application. The information submitted assists FDA in reviewing requests for an exception or alternative to the requirements for constituent materials. The Director of CBER or CDER would use the information collected to approve, as appropriate, a manufacturer's request for an exception or alternative.

3. Use of Improved Information Technology and Burden Reduction

One of FDA's continuing objectives is to improve the speed and quality of its review and approval programs. To make the review process more efficient for industry and FDA, CBER and CDER utilize electronic information system technology. CBER and CDER currently accept the submission of electronic license applications. FDA believes the increased use of computer-assisted information technology, such as regulatory submissions in electronic format, enhances the timeliness, effectiveness, and efficiency of the review process and reduces burdensome, nonessential hard-copy handling and storage. FDA is not aware of any other improved technology to reduce the burden.

FDA continues to pursue methods of applying technology to further reduce the burden to the respondents of the collection of information.

4. Efforts to Identify Duplication and Use of Similar Information

FDA is the only agency that requires the request for an exception or alternative to certain requirements for constituent materials applicable to biological products. No other government agency requires similar information or data to be submitted. This information is not available from any other source.

5. Impact on Small Businesses or Other Small Entities

Although FDA must apply the statutory and regulatory requirements equally to all enterprises, FDA does provide special help to small businesses. CBER's Office of Communications, Outreach and Development, Division of Manufacturers Assistance and Training, and CDER's Office of Communication, Division of Drug Information, provides assistance to small businesses subject to FDA's regulatory requirements.

6. Consequences of Collecting the Information Less Frequently

A manufacturer may request an exemption or alternative to the regulation for constituent materials and would be required to submit the necessary information only when making such a request. Less frequent collection of this information would not provide the information that FDA needs to assess the safety, purity, and potency of a biological product in a timely manner.

There are no technical or legal obstacles to reducing the burden.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

A manufacturer may be required to submit to FDA proprietary trade secret or other confidential information when submitting a request for an exception or alternative to the requirements. FDA protects the confidential information received from manufacturers to the extent permitted by law.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency.

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the Federal Register of November 29, 2012 (77 FR 71193). No public comments were received.

9. Explanation of Any Payment or Gift to Respondents

No payment or gift was provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

The confidentiality of information received by FDA is consistent with the Freedom of Information Act (FOIA) and FDA's regulations under 21 CFR Part 20 (Public Information) and 21 CFR 601.51.

11. Justification for Sensitive Questions

Questions of a sensitive nature are not applicable to this collection of information.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

The total annual estimated burden for this collection of information is 1 hour.

Table 1. -- Estimated Annual Reporting Burden					
21 CFR Part	No. of respondents	No. of responses per respondent	Total annual responses	Average burden per Response	Total Hours
610.15(d)	1	1	1	1	1

Since the implementation of the final rule in May 2011, FDA has received no submissions of requests for an exception or alternative for constituent materials. Therefore, FDA is estimating one respondent and one annual response to account for a possible submission to CBER or CDER of a request for an exception or alternative for constituent materials under § 610.15(d). The average burden per response (1 hour) is based on FDA experience with similar information collection requirements.

12b. Annualized Cost Burden Estimate

The estimated annual cost to respondents is $51.

Activity	No. of Hours	Cost per Hour	Total Cost
Reporting	1	$51	$51

The cost estimate is based on a regulatory affairs specialist, at a pay rate of $ 51/hour, who would be responsible for preparing and submitting a request for an exception or alternative. The estimated cost includes benefits but no overhead costs.

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers/Capital Costs

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

The estimated annual cost to FDA is $67.

Activity	Number of Reviews	Review/Process Time	Average Cost per Hour	Total Cost
Review and Process	1	1	$67	$67

The estimated cost to the Federal Government is based on FDA regulatory review staff with an average pay of $67/hour spending an estimated average of 1 hour to review and process the request submitted to FDA. The estimated cost includes benefits but no overhead costs.

15. Explanation for Program Changes or Adjustments

The previous estimated total annual burden was 3 hours. The current decrease in burden to 1 hour (-2 hours) is based upon data from FDA since the implementation of the final rule in May 2011.

FDA intends to consolidate this information collection at the next extension request of OMB Control No. 0910-0338 (expires 12/31/2013).

16. Plans for Tabulation and Publication and Project Time Schedule

There are no tabulated results to publish for this collection of information.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

FDA is not seeking approval to exempt the display of the expiration date of the OMB approval.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.