Revision of the Requirements Constituent Material; Proposed Rule

0910-[NEW]

SUPPORTING STATEMENT

Justification

1. Circumstances Making the Collection of Information Necessary

The Food and Drug Administration (FDA) is requesting Office of Management and Budget (OMB) approval of the information collection provision listed below:

21 CFR 610.15(d)	Reporting	Manufacturers seeking approval of an exception or alternative to any requirement in this section must submit a request in writing to the Director of the Center for Biologics and Research or the Director of the Center for Drug Evaluation and Research.

FDA is amending the regulation for constituent materials at § 610.15 to allow the Director of Center for Biologics Evaluation and Research (CBER) or the Director of the Center for Drug Evaluation and Research (CDER), as appropriate, to approve an exception or alternative to the requirements under § 610.15, when data submitted with the exception or alternative establish the safety, purity, and potency of the biological product.

FDA is taking this action due to advances in science and technology for developing and manufacturing safe, pure, and potent biological products licensed under section 351 of the Public Health Service Act, that in some instances, render the existing constituent materials regulation too prescriptive and unnecessarily restrictive. The proposed rule provides manufacturers of licensed biological products with flexibility, as appropriate, to employ advances in science and technology as they become available, without diminishing public health protections.

FDA is issuing 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 disease.

2. Purpose and Use of the Information Collection

Manufacturers of biological products 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 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 to be collected will assist FDA in identifying and 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.. This would provide manufacturers with flexibility to employ advances in science and technology as they become available, without diminishing public health protections.

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.

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 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.

   The proposed rule provides a 30-day notice requesting public comment on the information collection provision.

9. Explanation of Any Payment or Gift to Respondents

   No payment or gift has been or will be provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

    The confidentiality of information received by FDA would be consistent with the Freedom of Information Act (FOIA) and FDA's published regulations under 21 CFR Part 20 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

    The total annual estimated burden imposed by this collection of information is 3 hours.

Table 1. -- Estimated Annual Reporting Burden

21 CFR	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
610.15	3	1	3	1	3

Based on FDA experience, FDA estimates that it will receive a total of approximately 3 requests annually for an exception or alternative under § 610.15. The hours per response are based on FDA experience with similar information collection requirements.

Cost to Respondents

The estimated annual cost to respondents is $138.

Activity	No. of Hours	Cost per Hour	Total Cost
Reporting	3	$46	$138

The cost estimate is based on a regulatory affairs specialist, at a pay rate of $ 46/hour, who would be responsible for preparing a request for an exception or alternative. The estimated average hourly pay rate includes benefits but no overhead costs.

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

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

14. Annualized Cost to the Federal Government

The estimated annual cost to FDA is $183.

Activity	Number of Reviews	Review/Process Time	Average Cost per Hour	Total Cost
Review and Process	3	1	$61	$183

This estimate is based on FDA regulatory review staff with an average pay of $61/hour spending an estimated average of 1 hour to review and process the request submitted to FDA. This salary estimate includes benefits but no overhead costs.

15. Explanation for Program Changes or Adjustments

There is no change in burden as this is the first submission of the proposed rule.

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

N/A.