Guidance for Industry: Cooperative Manufacturing Arrangements for Licensed Biologics

0910-0629

SUPPORTING STATEMENT

A. 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 provisions contained in the above-referenced guidance document (Tab A). The information collection provisions are listed below:

Notification of all important proposed changes to production and facilities	Reporting	Recommends (for a divided manufacturing arrangement or shared manufacturing arrangement) that each licensed manufacturer that proposes such a change should inform the other participating licensed manufacturer(s) of the proposed change.
		Recommends (for contract manufacturing arrangements) that the contract manufacturer should share with the license manufacturer all important proposed changes to production and facilities (including introduction of new products or at inspection).
Notification of results of tests and investigations regarding or possibly impacting the product	Reporting	Recommends (for contract manufacturing arrangements) that the contract manufacturer should fully inform the license manufacturer of the results of all tests and investigations regarding or possibly having an impact on the product.
		Recommends (for contract manufacturing arrangements) that the license manufacturer should obtain assurance from the contractor that any FDA list of inspectional observations will be shared with the license manufacturer to allow evaluation of its impact on the purity, potency, and safety of the license manufacturer's product.
Notification of products manufactured in a contract facility	Reporting	Recommends (for contract manufacturing arrangements) that a license manufacturer cross reference a contract manufacturing facility's Master Files only in circumstances involving certain proprietary information of the contract manufacturer such as a list of all products manufactured in a contract facility. In this situation, the license manufacturer should be kept informed of the types or categories of all products manufactured in the contract facility.

Standard Operating Procedures	Recordkeeping	Reminds (for contract manufacturing arrangements) the license manufacturer that an agreement between a license manufacturer and a contract manufacturing facility normally includes procedures to regularly assess the contract manufacturing facility's compliance with the applicable product and establishment standards.
		Recommends (for shared manufacturing arrangements) that the final product manufacturer establish a procedure with the other participating manufacturer(s) to obtain certain information relating to the final product and post-approval obligations.

The guidance document provides information concerning cooperative manufacturing arrangements applicable to biological products subject to licensure under section 351 of the Public Health Service Act (PHS Act) (42 U.S.C. 262). The guidance document addresses several different types of cooperative manufacturing arrangements (i.e., short supply arrangements, divided manufacturing arrangements, shared manufacturing arrangements and contract manufacturing arrangements). The guidance document describes certain reporting and recordkeeping responsibilities associated with these arrangements, including the following: (1) Notification of all important proposed changes to production and facilities, (2) notification of results of tests and investigations regarding or possibly impacting the product, (3) notification of products manufactured in a contract facility, and (4) standard operating procedures (SOPs).

This information collection is not related to the American and Reinvestment Act of 2009 (ARRA).

2. Purpose and Use of the Information Collection

The sharing of the requested information provides the appropriate parties with the necessary information regarding any cooperative manufacturing arrangements. The SOPs ensure that established written procedures are followed.

3. Use of Improved Information Technology and Burden Reduction

Respondents can use computers, computer discs, microfiche, microfilm, etc. to record and store data and information rather than hard copy records. 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 this information. There is no similar kind of information available from any other source.

5. Impact on Small Businesses or Other Small Entities

The information collection provided in the guidance applies to small as well as large facilities.

However, FDA believes there is no impact on small business since this information collection is part of usual and customary business practice. While FDA does not believe it can apply different standards with respect to regulatory requirements, FDA does provide special help to small businesses. The Center for Biologics Evaluation and Research (CBER), Office of Communication, Training, and Manufacturers Assistance, and the Center for Drug Evaluation and Research (CDER), Office of Training and Communication, provide assistance to small businesses subject to FDA's regulatory requirements.

6. Consequences of Collecting the Information Less Frequently

Less frequent collection of information would not provide the information that FDA needs to properly assure that biological products manufactured under cooperative manufacturing arrangements are safe, pure, and potent. There are no technical or legal obstacles to reducing the burden.

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

There are no special circumstances for this collection of information.

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

In accordance with 5 CFR 1320.8, FDA published a 60-day notice for public comment in the Federal Register of March 16, 2011 (76 FR 14405). No 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 would be consistent with the Freedom of Information Act (FOIA) and the FDA's published regulations of "Public Information" under 21 CFR Part 20, and of public disclosure of data or confidentiality of data under 21 CFR 312.130, 314.430, 601.50, 601.51, 807.95, 809.4, 812.38, and 814.122.

11. Justification for Sensitive Questions

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

12. Estimates of Annualized Burden Hours and Costs

Respondents to this collection of information are licensed manufacturers, final product manufacturers, and contract manufacturers associated with cooperative manufacturing arrangements.

FDA believes that the information collection provisions mentioned in the guidance document do not create a new burden for the respondents. FDA believes the reporting and recordkeeping provisions mentioned in the guidance are part of the usual and customary

business practice. Licensed manufacturers would have contractual agreements with participating licensed manufacturers, final product manufacturers, and contract manufacturers, as applicable for the type of cooperative manufacturing arrangement, to address all these information collection provisions.

For example, a list of all product types manufactured in a contract facility (e.g., contract filler for vaccines) would be part of a contractual agreement. The contract facility provides this information to FDA in a Master File and the licensed manufacturer provides a cross-reference to the Master File as part of their license application.

The guidance also refers to previously approved collections of information found in FDA regulations at 21 CFR Parts 201, 207, 211, 600, 601, 606, 607, 610, 660, 801, 803, 807, 809, and 820. The collections of information in §§ 606.121, 606.122, and 610.40 have been approved under OMB Control No. 0910-0116; § 610.2 has been approved under OMB Control No. 0910-0206; §§ 600.12(e) and 600.80 have been approved under OMB Control No. 0910-0308; §§ 601.2(a), 601.12, 610.60 through 610.65, 610.67, 660.2(c), 660.28(a) and (b), 660.35(a), 660.35(c) through (g), 660.35(i) through (m), 660.45, and 660.55(a) and (b) have been approved under OMB Control No. 0910-0338; §§ 803.20, 803.50, and 803.53 have been approved under OMB Control No. 0910-0437; and §§ 600.14 and 606.171 have been approved under OMB Control No. 0910-0458. The current good manufacturing practice regulations for finished pharmaceuticals (Part 211) have been approved under OMB Control No. 0910-0139; §§ 820.181 and 820.184 have been approved under OMB Control No. 0910-0073; the establishment registration regulations (Parts 207, 607, and 807) have been approved under OMB Control Nos. 0910-0045, 0910-0052, and 0910-0387; and the labeling regulations (Part 201, 801, and 809) have been approved under OMB Control Nos. 0910-0537, 0910-0572 and 0910-0485.

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

There is no estimated annual cost to the Federal Government for this collection of information.

15. Explanation for Program Changes or Adjustments

Burden changes are not applicable because the guidance document has not changed since the last renewal.

16. Plans for Tabulation and Publication and Project Time Schedule

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

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

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

18. Exceptions to Certification for Paperwork Reduction Act Submissions

Not Applicable.