Supporting Statement for
Draft Guidance for Industry: Cooperative Manufacturing Arrangements for Licensed Biologics
OMB No. 0910-XXXX

A. JUSTIFICATION

1. Need and Legal Basis

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of Management and Budget (OMB) approval of the information collection provisions contained in the above-referenced draft guidance document (Tab A). The information collection provisions are listed below:

Notification of any proposed change in the product, production process, quality controls or facility	Reporting	Recommends (for a divided manufacturing arrangement or shared manufacturing arrangement) that each licensed manufacturer that proposes changes in the manufacture, testing, or specifications of its product should inform 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 related to or 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) that an agreement between a license manufacturer and a contract manufacturing facility normally includes certain 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 postapproval obligations.

The guidance document referred to in the title of this submission 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) (Tab B). The guidance document addresses several different types of cooperative manufacturing arrangements such as short supply arrangements, divided manufacturing arrangements, shared manufacturing arrangements, and contract manufacturing arrangements. The guidance document describes the various reporting and recordkeeping requirements as well as the responsibilities, on the part of the licensed manufacturer(s), contract manufacturer(s), and final product manufacturer(s) associated with each different type of cooperative manufacturing arrangement.

2. Information Users

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. Improved Information Technology

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. Duplication 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. Small Businesses

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. Less Frequent Collection

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

There is no special circumstance for the collection of information requirements.

8. *Federal Register* Notice/Outside Consultation

In accordance with 5 CFR 1320.8(d), on July 23, 2007, in Volume 72, No. 140, page 40157, a 60-day notice for public comment was published in the FEDERAL REGISTER. FDA received four letters of comment from the public. None of the comments pertained to the proposed collection of information.

9. Payment/Gift to Respondent

No payment or gift was provided to respondents.

10. Confidentiality

The confidentiality of information received by FDA is consistent with the Freedom of Information Act (FOIA) and the FDA's regulations under 21 CFR Part 20. Inspectors may copy records as part of an inspection. This information is for internal use only and would be redacted from any information released by FDA under FOIA and FDA regulations.

11. Sensitive Questions

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

12. Burden Estimate (Total Hours and Wages)

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.

This draft 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, 803, and 807.

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, 610.61, 610.62, 610.67, 660.2(c), 660.28(a) and (b), 660.35(a), (c) through (g), and (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; 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) have been approved under OMB Control Nos. 0910-0340 and 0910-0370.

13. Capital Costs (Maintenance of Capital Costs)

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

14. Cost to Federal Government

There is no estimated annual cost to the Federal Government for the collections of information mentioned in the guidance document.

15. Program or Burden Changes

Program or burden changes are not applicable as this is the first submission for the guidance document.

16. Publication and Tabulation Dates

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

17. Display of OMB Approval Date

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.