U.S. Food and Drug Administration
Guidance for Industry (GFI); Cooperative Manufacturing Arrangements for Licensed Biologics

OMB Control No. 0910-0629

SUPPORTING STATEMENT **Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA) guidance entitled "*Guidance for Industry; Cooperative Manufacturing Arrangements for Licensed Biologics*." The guidance document provides information concerning the various cooperative manufacturing arrangements used in the production of biological products subject to licensure under section 351 of the PHS Act (42 U.S.C. 262). It describes FDA's current thinking on licensing strategies for meeting the increased need for planning flexible manufacturing arrangements. Because cooperative manufacturing arrangements can take a considerable amount of time to develop, the guidance may be useful for planning purposes in the early phases of product development. Several types of manufacturing arrangements discussed in the guidance include short supply arrangements, divided manufacturing arrangements, shared manufacturing arrangements, and contract manufacturing arrangements. These recommendations contain certain information collection suggestions including:

Activity	*Description*
Reporting: Notification of all important proposed changes to production and facilities	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).
Reporting: Notification of results of tests and investigations regarding or possibly impacting the product	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.

Activity	*Description*
Reporting: Notification of products manufactured in a contract facility	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.
Recordkeeping: Standard Operating Procedures	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. These procedures may include, but are not limited to review of records and manufacturing deviations and defects, and periodic audits.
	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, such as postmarketing clinical trials, additional product stability studies, complaint handling, recalls, postmarket reporting of the dissemination of advertising and promotional labeling materials as required under §21 CFR 601.12(f)(4) and adverse experience reporting.

Although we believe these activities impose no burden on respondents beyond those considered usual and customary business practice, we retain a nominal burden estimate and continue to invite public comment on the information collection consistent with PRA regulations. Since establishment of the collection we have received no comments to warrant revising this estimate and therefore request extension of OMB approval.

2. Purpose and Use of the Information Collection

The development of complex and highly specialized technology and equipment for the manufacture of biological products has fostered the emergence of many companies that perform only limited aspects of manufacturing processes. Consequently, many manufacturers are interested in sharing or contracting parts of manufacturing in order to facilitate product development and manufacturing flexibility. Cooperative manufacturing arrangements enhance the development of new products.

3. Use of Improved Information Technology and Burden Reduction

Notifications can be accomplished by e-mail, fax, or mail. Respondents can use computers, computer discs, tapes, microfiche, or microfilm, etc., in lieu of hard copy records for the purpose of maintaining records. FDA is not aware of any other improved technology to reduce the burden.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection. However, respondents should note the guidance document discusses a broad range of topics and makes reference to several agency regulations supported by individually established ICRs, including but not necessarily limited to currently approved OMB Control Nos. 0910-0116; 0910-0139; 0910-0206; 0910-0308; 0910-0338; 0910-0437; 0910-0458; 0910-0045; 0910-0052; 0910-0073; 0910-0625; 0910-0537; 0910-0572; and 0910-0485.

5. Impact on Small Businesses or Other Small Entities

The information collection provided in the guidance applies to small as well as large facilities. Although FDA must apply the statutory and regulatory requirements to all enterprises, FDA does provide special help to small businesses. The Center for Biologics Evaluation and Research (CBER), Office of Communication, Outreach, and Development, Division of Manufacturer's Assistance and Training, and the Center for Drug Evaluation and Research (CDER), Office of Communication, Division of Drug Information provide assistance to small businesses subject to FDA's regulatory requirements.

6. Consequences of Collecting the Information Less Frequently

Information collection schedule is consistent with guidance recommendations.

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 August 7, 2017, (82 FR 36797). 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 the FDA's published regulations under 21 CFR Part 20, 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 are not applicable to this information collection.

12. Estimates of Annualized Burden Hours and Costs

As previously discussed, FDA believes that the information collection provisions found in the guidance document create no new burden for respondents. Rather, we believe the reporting and recordkeeping provisions are part of usual and customary business practice associated with licensed biological establishment practice. For example, we expect licensed manufacturers to already have available information referenced in the guidance such as contractual agreements with participating licensed manufacturers, final product manufacturers, and contract manufacturers. Likewise, we expect respondents already retain listings of all product types manufactured in a contract facility (e.g., contract filler for vaccines) that are 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 its license application. We therefore retain a nominal burden of one respondent and one burden hour; however, FDA continues to invite public comment on the information collection consistent with PRA requirements.

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers

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

15. Explanation for Program Changes or Adjustments

We retain the currently approved burden estimate for the information collection.

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

Display of the OMB Expiration Date is appropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.