UNITED STATES FOOD & DRUG ADMINISTRATION

Request for Samples and Protocols

OMB Control No. 0910-0206

SUPPORTING STATEMENT – **Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, us or we) regulations. Under section 351 of the Public Health Service Act (42 U.S.C. 262), FDA has the responsibility to issue regulations that prescribe standards designed to ensure the safety, purity, and potency of biological products and to ensure that the biologics licenses for such products are only issued when a product meets the prescribed standards. Under § 610.2 (21 CFR 610.2), the Center for Biologics Evaluation and Research (CBER) or the Center for Drug Evaluation and Research (CDER) may at any time require manufacturers of licensed biological products to submit to FDA samples of any lot, along with the protocols showing the results of applicable tests, prior to distributing the lot of the product. In addition to § 610.2, there are other regulations that require the submission of samples and protocols for specific licensed biological products: §§ 660.6, 660.36, and 660.46 (21 CFR 660.6, 660.36, and 660.46). We are requesting extension of OMB approval for the information collection provisions associated with the applicable regulations and discussed in this supporting statement.

2. Purpose and Use of the Information Collection

Samples and protocols are required by FDA to help ensure the safety, purity, and potency of the product because of the potential lot-to-lot variability of a product produced from living organisms. In cases of certain biological products (e.g., Albumin, Plasma Protein Fraction, and therapeutic biological products) that are known to have lot-to-lot consistency, official lot release is not normally required. However, submissions of samples and protocols of these products may still be required for surveillance, licensing, and export purposes, or in the event that FDA obtains information that the manufacturing process may not result in consistent quality of the product. The written protocols are reviewed by FDA scientists and other staff with expertise in the appropriate product and scientific area. FDA tests samples to verify the manufacturer's test results. A manufacturer may not distribute a product until FDA gives the official release for the lot.

3. Use of Improved Information Technology and Burden Reduction

One of FDA's continuing objectives is to improve the timeliness and quality of its review and approval programs. FDA accepts electronic lot release protocols and has issued guidance to assist manufacturers in this area. FDA believes that the increased use of computer-assisted protocol submissions will enhance the timeliness, effectiveness, and efficiency of the review

process and reduce burdensome, nonessential hard-copy handling and storage.

We are not aware of any other improved technology to reduce the burden. We continue to pursue methods of applying technology to reduce the burden to the respondents of the information collection.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

The information collection poses no undue burden on respondents.

6. Consequences of Collecting the Information Less Frequently

The information collection schedule is consistent with applicable statutory and regulatory requirements and enables us to properly evaluate results of specific tests identified for lot release review in the license application. Less frequent collection may pose unnecessary risk to the public health. We are unaware of any technical or legal obstacles to reducing the burden.

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

An applicant may be required to submit to FDA proprietary trade secret or other confidential information when submitting a protocol. FDA protects confidential information received from manufacturers to the extent permitted by law. In addition, the frequency of submissions may be more often than quarterly depending on the number of lots produced for a product over that time.

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

In accordance with 5 CFR 1320.8(d), we published a 60-day notice in the *Federal Register* on March 16, 2021 (86 FR 14448), soliciting public comment on the information collection provisions. No comments were received.

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

In preparing this supporting statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected. Although personally identifiable information (PII) is collected, it is collected in the context of the subject individuals' professional capacity and the FDA-related work performed for their employer (e.g., point of contact at a regulated entity). The PII submitted with samples and protocols is name, address, telephone number, email address, and fax number. We have determined the PII collected is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Privacy Act do not apply. Specifically, the contractor or FDA do not use name or any other personal identifier to routinely retrieve records from the information collected. Through appropriate instruction, FDA limited submission fields and minimized the PII collected to protect the privacy of the individuals.

Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

11. Justification for Sensitive Questions

This information collection does not involve questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

Table 1.--Estimated Annual Reporting Burden[1]

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
610.2 Requests for samples and protocols; official release	72	82.972	5,974	3	17,922
660.6 Antibody to Hepatitis B surface antigen	3	4	12	5	60
660.36 Reagent red blood cells	1	1	1	6	6
660.46 Hepatitis B surface antigen	1	1	1	5	5
Total	77		5,988		17,993

[1] There are no capital costs or operating and maintenance costs associated with this collection of information

Our burden estimate is for the submission of protocols with each sample. Respondents to the collection of information under § 610.2 are manufacturers of licensed biological products. Respondents to the collection of information under §§ 660.6(b), 660.36(a)(2) and

(b), and 660.46(b) are manufacturers subject to those regulations, respectively. Our figures are based on agency data reflecting that approximately 75 manufacturers submitted samples and protocols in fiscal year (FY) 2020, and we attribute 72 to protocols submitted under § 610.2, and 3 to protocols submitted under § 660.6. No submissions were received under §§ 660.36 or 660.46; however, we retain our current estimate for any future submissions. Our average burden per response is based on informal communications with industry and ranges from 1 to 5.5 hours. For burden attributable to the remaining provisions we assume a higher end estimate of 6 hours.

12b. Annualized Cost Burden Estimate

Activity	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Reporting	17,993	$76	$1,367,468

Our annualized cost estimate assumes an average pay rate of $76.00/hour. This average is based on the salaries of an upper-level manager, a mid-level professional, and clerical support that may be involved in the preparation and submission of the protocol.

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

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

14. Annualized Cost to Federal Government

The estimated annualized cost to FDA is $988,020.00. The review of each protocol by FDA involves six persons, at an average pay rate of $55.00/hour, who spend approximately 3 hours per protocol. The estimate is based on FDA's final actions completed in FY 2020, which totaled 5,988. This estimate does not include the time related to the testing of samples, because the submission of samples is not a collection of information as defined under the PRA.

Activity	Number of Reviews	Review Time	Average Cost per Hour	Total Cost
Protocol Review	5,988	3 hrs.	$55	$988,020

15. Explanation for Program Changes or Adjustments

Our estimated burden for the information collection reflects an overall decrease of 1,463 hours and a corresponding decrease of 491 responses. We attribute this adjustment to a decrease in the number of submissions we received since our last evaluation of 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

FDA will display the OMB expiration date as required by 5 CFR 1320.5.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.