Guidance for Industry on Formal Meetings Between the FDA and Biosimilar Biological Product Sponsors or Applicants

0910-[NEW]

SUPPORTING STATEMENT

Terms of Clearance – None.

## A. Justification

1. Circumstances Making the Collection of Information Necessary

The Biologics Price Competition and Innovation Act of 2009 amended the Public Health Service Act (PHS Act) and other statutes to create an abbreviated licensure pathway in section 351(k) of the PHS Act (42 U.S.C. 262(k)) for biological products shown to be biosimilar to, or interchangeable with, an FDA-licensed biological product (see sections 7001 through 7003 of the Patient Protection and Affordable Care Act (Pub. L. 111–148)). The Biosimilar User Fee Act of 2012 (BsUFA), enacted as part of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144), amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to authorize a new user fee program for biosimilar biological products. FDA has committed to meeting certain performance goals in connection with the new user fee program. The performance goals, which are set forth in a letter from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, include meeting management goals for formal meetings that occur between FDA and sponsors or applicants during the development phase of a biosimilar biological product. This guidance describes the Agency's current thinking on how it intends to interpret and apply

certain provisions of BsUFA, and also provides information on specific performance goals for the management of meetings associated with the development and review of biosimilar biological products.

This guidance reflects a unified approach to all formal meetings between sponsors or applicants and FDA for biosimilar biological product development (BPD) programs. It is intended to assist sponsors and applicants in generating and submitting a meeting request and the associated meeting package to FDA for biosimilar biological products. This guidance does not apply to new drug or abbreviated new drug applications under section 505 of the FD&C Act or to biologics license applications under section 351(a) of the PHS Act.

FDA expects that review staff will participate in many meetings with biosimilar biological product sponsors or applicants who seek guidance relating to the development and review of biosimilar biological products. Because these meetings often will represent critical points in the regulatory process, it is important that there are efficient, consistent procedures for the timely and effective conduct of such meetings. The good meeting management practices in this guidance are intended to provide consistent procedures that will promote well-managed meetings and to ensure that such meetings are scheduled within a reasonable time, conducted efficiently, and documented appropriately. The following five meeting types that occur between sponsors or applicants and FDA staff during the biosimilar BPD phase are described in the guidance: (1) Biosimilar Initial Advisory meeting; (2) BPD Type 1 meeting; (3) BPD Type 2 meeting; (4) BPD Type 3 meeting; and (5) BPD Type 4 meeting.

2. Purpose and Use of the Information Collection

The guidance provides recommendations to industry on formal meetings between FDA and sponsors or applicants relating to the development and review of biosimilar biological products regulated by CDER and CBER. For the purposes of this guidance, "formal meeting" includes any meeting that is requested by a sponsor or applicant following the request procedures provided in this guidance and includes meetings conducted in any format (i.e., face to face, teleconference, or videoconference).

3. Use of Improved Information Technology and Burden Reduction

FDA provides guidance on the electronic submission of information related to marketing applications at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm064994.htm

4. Efforts to Identify Duplication and Use of Similar Information

The requirements do not duplicate nor are they similar to any current procedures for requesting meetings.

5. Impact on Small Businesses or Other Small Entities

The guidance applies to formal meetings between FDA and any sponsor or applicant relating to the development and review of biosimilar biological products regulated by CDER and CBER. The submissions provide FDA staff the opportunity to adequately prepare for the meeting, including the review of relevant data concerning the product.

6. Consequences of Collecting the Information Less Frequently

The guidance assists sponsors and applicants in generating and submitting meeting requests and the associated meeting packages to FDA for biosimilar biological products.

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

There are no special circumstances relating to this information collection.

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

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice in the FEDERAL REGISTER of April 1, 2013 (78 FR 19492). None of the comments pertained to the information collection provisions in the draft guidance.

9. Explanation of Any Payment or Gift to Respondents

There is no payment or gift to respondents associated with this guidance.

10. Assurance of Confidentiality Provided to Respondents

Confidentiality of the information submitted under the guidance is protected under 21 CFR part 20. The unauthorized use or disclosure of trade secrets is specifically prohibited under Section 310(j) of the FD&C Act.

11. Justification for Sensitive Questions

There are no sensitive questions associated with this guidance.

12. Estimates of Annualized Hour Burden and Costs

12a. Annualized Hour Burden Estimate

The guidance describes two types of collections of information: (1) The submission of a meeting request containing certain information; and (2) the submission of an information package that accompanies the meeting request. The guidance also refers to previously approved collections of information found in FDA regulations. The collections of information for 21 CFR 312.48 have been approved under OMB control number 0910-0014.-

A. Request for a Meeting

Under the guidance, a sponsor or applicant interested in meeting with CDER or CBER should submit a meeting request to the sponsor's or applicant's application (e.g., investigational new drug application, BLA) through the controlled document system. If there is no application, the request should be submitted to either the appropriate CDER division director with a copy sent to the division's chief of project management staff or to the division director of the appropriate product office within CBER. Before submitting any meeting request by fax or email when there is no application, the sponsor or applicant should contact the appropriate review division or the Biosimilars Program staff, CDER, Office of New Drugs, to determine to whom the request should be directed, how the request should be submitted, and the appropriate format for the request, and to arrange for confirmation of receipt of the request.

FDA recommends that a request be submitted in this manner to prevent the possibility of faxed or emailed requests being overlooked because of the volume of emails received daily by FDA staff. Faxed or emailed requests should be sent during official business hours (8 a.m. to 4:30 p.m. EST/EDT) Monday through Friday (except Federal government holidays). Processing and receipt may be delayed for requests where confirmation of receipt has not been prearranged.

Under the draft guidance, FDA requests that sponsors and applicants include in meeting requests certain information about the proposed meeting. This information includes:

1. Product Name.
2. Application Number (if applicable).
3. Proposed Proper Name (or proper name if post-licensure).
4. Structure (if applicable).
5. Reference Product Name.
6. Proposed Indication(s) or Context of Product Development.
7. Meeting Type Being Requested (i.e., Biosimilar Initial Advisory meeting, BPD Type 1, 2, 3, or 4 meeting). The rationale for requesting the meeting type should be included.
8. A Brief Statement of the Purpose of the Meeting. This statement should include a brief background of the issues underlying the agenda. It also can include a brief summary of completed or planned studies and clinical trials or data that the sponsor or applicant intends to discuss at the meeting, the general nature of the critical questions to be asked, and where the meeting fits in overall development plans. Although the statement need not provide detailed documentation of trial designs or completed studies and clinical trials, it should provide enough information to facilitate understanding of the issues, such as a small table that summarizes major results.
9. A List of the Specific Objectives/Outcomes the Requester Expects from the Meeting.
10. A Proposed Agenda, Including Estimated Times Needed for Each Agenda Item.

11. A List of Questions, Grouped by Discipline. For each question there should be a brief explanation of the context and purpose of the question.

12. A List of Ill Individuals with Their Titles and Affiliations Who Will Attend the Requested Meeting from the Sponsor's or Applicant's Organization and Consultants.

13. A List of FDA Staff, if Known, or Disciplines, Asked to Participate in the Requested Meeting.

14. Suggested Dates and Times (e.g., morning or afternoon) for the Meeting Which are Within or Beyond the Appropriate Time Frame of the Meeting Type Being Requested.

15. The Proposed Format of the Meeting (i.e., face-to-face meeting, teleconference, or videoconference).

This information will be used by FDA to determine the utility of the meeting, to identify FDA staff necessary to discuss proposed agenda items, and to schedule the meeting.

B. Information Package

FDA requests that a sponsor or applicant submit a meeting package to the appropriate review division with the meeting request. FDA recommends that information packages generally include:

1. Product Name and Application Number (if applicable).

2. Proposed Proper Name (or proper name if postlicensure).

3. Structure (if applicable).

4. Reference Product Name.

5. Proposed Indication(s) or Context of Product Development.

6. Dosage Form, Route of Administration, Dosing Regimen (frequency and duration), and Presentation(s).

7. A List of Sponsor or Applicant Attendees, Affiliations, and Titles.

8. A Background Section that Includes the Following:

a. *A brief history of the development program*.

b. *The status of product development (e.g., chemistry, manufacturing, and controls; nonclinical; and clinical, including any development outside the United States, as applicable).*

2. A Brief Statement Summarizing the Purpose of the Meeting.

3. A Proposed Agenda.

4. A List of Questions for Discussion Grouped by Discipline and with a Brief Summary for Each Question to Explain the Need or Context for the Question.

5. Data to Support Discussion Organized by Discipline and Question. The level of detail of the data should be appropriate to the meeting type requested and the product development stage.

The purpose of the information package is to provide FDA staff the opportunity to adequately prepare for the meeting, including the review of relevant data concerning the product.

Description of Respondents: A sponsor or applicant for a biosimilar biological product who requests a formal meeting with FDA regarding the development and review of a biosimilar biological product.

Burden Estimate: Provided below is an estimate of the annual reporting burden for the submission of meeting requests and information packages under the draft guidance.

The estimated number of respondents submitting meeting requests and information packages is based on the current workload and development expectations for biosimilar biological products. The burden hour estimate includes any time that may be needed by sponsors or applicants for rescheduling and canceling meetings, for premeetings and other communications with FDA about the meetings, and for resolution of disputes about meeting minutes.

Based on the current workload and development expectations, FDA estimates that approximately 15 sponsors and applicants (respondents) may request approximately a total of 30 formal meetings, and submit approximately 30 information packages, with CDER annually, and approximately 1 respondent may request approximately 2 formal meetings, and submit approximately 2 information packages, with CBER annually.

For a meeting request, the hours per response, which is the estimated number of hours that a respondent would spend preparing the information to be submitted with a meeting request in accordance with the guidance, is estimated to be approximately 15 hours. Based on FDA's experience, we expect it will take respondents this amount of time to gather and copy brief statements about the product and a description of the purpose and details of the meeting.

For an information package, the hours per response, which is the estimated number of hours that a respondent would spend preparing the information package in accordance with the draft guidance, is estimated to be approximately 30 hours. Based on FDA's experience, we expect it will take respondents this amount of time to gather and copy brief statements about the product, a description of the details for the anticipated meeting, and data and information that generally would already have been compiled for submission to FDA. In total, we expect

sponsors to spend 480 hours preparing meeting requests and 960 hours preparing information packages each year.

Table 1.--Estimated Annual Reporting Burden

| Draft Guidance for Industry on Formal Meetings Between FDA and Biosimilar Biological Product Sponsors or Applicants | No. of Respondents | No. of Responses per Respondent | Total Annual Responses | Average Burden per Response | Total Hours |
|---|---|---|---|---|---|
| Meeting Requests: | | | | | |
| CDER | 15 | 2 | 30 | 15 | 450 |
| CBER | 1 | 2 | 2 | 15 | 30 |
| Total | | | | | 480 |
| Information Packages: | | | | | |
| CDER | 15 | 2 | 30 | 30 | 900 |
| CBER | 1 | 2 | 2 | 30 | 60 |
| Total | | | . | | 960 |
| Total | | | | | 1,440 |

12b. Annualized Cost Burden Estimate

The industry burden estimate calculated above would result in labor costs. The submissions are generally made by a regulatory affairs manager; labor hours are valued using the mean hourly wage of $63.89 as reported by the U.S. Department of Labor, Bureau of Labor Statistics, 2013 Employment Occupational Statistics for Management Occupations (SOC 11-0000) in Pharmaceutical and Medicine Manufacturing (North American Industry Notification, NAICS, code 325400). Wages are further adjusted for benefits and overhead, for an average hourly labor cost of $127.78 ($63.89 x 2). Using this wage rate, times 1440 hours calculated above for this information collection, equals approximately $184,003.20 in labor costs.

13. Estimates of Other Total Annual Cost Burden 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 the Federal Government

The FDA burden to review and participate in meetings to discuss the development and review of biosimilar biological products would be part of the overall annualized Federal cost approved by OMB for the information collection entitled "General Licensing Provisions: Biologics License Application, Changes to an Approved Application, Labeling, Revocation and Suspension, Postmarketing Studies Status Reports, and Forms FDA 356h and 2567 (OMB Control # 0910-0338)." This estimated cost is as follows:

The estimated annualized cost to FDA is $12,482,982. This estimate is based on full-time equivalents (FTEs) associated with the review of license applications including supplemental applications. The amount of time and expense incurred by the Federal government includes the time to the review of all material submitted with an application or supplement. This information is essential to determine the safety and effectiveness of products in support of FDA's mission to protect the public health. This information may include clinical data, safety updates, samples submitted for evaluation by the agency, case report tabulations, case report forms, and patient information. The estimated average annual salary for FDA reviewers includes benefits but no overhead costs.

| Activity | Number of FTEs | Average Annual Reviewer Salary | Total Cost |
|---|---|---|---|
| Application/Supplement Review | 103 | $121,194 | $12,482,982 |

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no plans for tabulation and publication and project time scheduling.

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

The OMB expiration data will be displayed where required.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.