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Dated: March 18, 2013.

Tanja Popovic,

Deputy Associate Director for Science, Centers for Disease Control and Prevention.

[FR Doc. 2013–07204 Filed 3–29–13; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0286]

Draft Guidance for Industry on Formal Meetings Between FDA and Biosimilar Biological Product Sponsors or Applicants; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Formal Meetings Between the FDA and Biosimilar Biological Product Sponsors or Applicants.'' This draft guidance provides recommendations to industry on formal meetings between FDA and sponsors or applicants relating to the development and review of biosimilar biological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 the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER). The guidance assists sponsors and applicants in generating and submitting a meeting request and the associated meeting package to FDA for biosimilar biological products.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by May 31, 2013. Submit either electronic or written comments concerning the proposed collection of information by May 31, 2013.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002, or Office of Communication, Outreach, and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Neel Patel, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6483, Silver Spring, MD 20993–0002, 301–796–0970; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Formal Meetings Between the FDA and Biosimilar Biological Product Sponsors or Applicants.'' This draft 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 draft guidance, ''formal meeting'' includes any meeting that is requested by a sponsor or applicant following the request procedures provided in this draft guidance and includes meetings conducted in any format (i.e., face-to-face meeting, teleconference, or videoconference).

The Biologics Price Competition and Innovation Act of 2009 amended the Public Health Service (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,[1] 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 draft 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 draft 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 draft 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 (BLAs) under section 351(a) of the PHS Act.

FDA expects that review staff will participate in many meetings with biosimilar biological product sponsors

[1] See *http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/UCM281991.pdf.*

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 draft 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 draft 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.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on formal meetings between FDA and sponsors or applicants regarding biosimilar biological products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

III. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501–3520, Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

The draft guidance on the procedures for formal meetings between FDA and biosimilar biological product sponsors or applicants describes procedures for requesting, scheduling, conducting, and documenting such formal meetings.

The draft 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 draft 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 draft 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).*

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

10. A Proposed Agenda.

11. 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.

12. 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 draft 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 [1]

Draft guidance for industry on formal meetings between FDA and biosimilar biological product sponsors or applicants	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (hours)	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

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

IV. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm* or *http://www.regulations.gov.*

Dated: March 27, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–07445 Filed 3–29–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0295]

Draft Guidance for Industry on Scale-Up and Post-Approval Changes: Manufacturing Equipment Addendum; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a scale-up and post-approval changes (SUPAC) draft guidance for industry entitled ''SUPAC: Manufacturing Equipment Addendum.'' This revised draft document combines and supersedes ''SUPAC IR/MR: Immediate Release and Modified Release Solid Oral Dosage Forms: Manufacturing Equipment Addendum,'' published on January 1, 1999; and ''SUPAC–SS: Nonsterile Semisolid Dosage Forms; Manufacturing Equipment Addendum,'' published as a draft on December 1, 1998. FDA has now revised the draft manufacturing equipment addenda to remove the equipment examples and to clarify the types of processes being referenced.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance and on any other part of the SUPAC guidance series, submit either electronic or written comments on the draft guidance by July 1, 2013.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Jon Clark, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–2400.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a SUPAC draft guidance for industry entitled ''SUPAC: Manufacturing Equipment Addendum.'' This revised draft document combines and supersedes the following guidances for industry: (1) ''SUPAC IR/MR: Immediate Release and Modified Release Solid Oral Dosage Forms: Manufacturing Equipment Addendum,'' published on January 1, 1999, and (2) ''SUPAC–SS: Nonsterile Semisolid Dosage Forms; Manufacturing Equipment Addendum,'' published as draft on December 1, 1998. When published, these guidances included tables that listed specific equipment that were misinterpreted as a list of FDA required equipment. In addition, FDA is concerned that the equipment addenda may no longer reflect current practices and may be limiting, instead of encouraging, manufacturers to continually evaluate and update practices. FDA has removed the tables listing specific manufacturing equipment from these guidances and combined them into a single addendum. FDA has also made some changes to clarify the types of processes being referenced.

This guidance should be used with the following guidances for industry to determine what documentation should be submitted to FDA regarding equipment changes: (1) ''SUPAC–IR: Immediate Release Solid Oral Dosage Forms—Scale-Up and Post-Approval Changes: Chemistry, Manufacturing and Controls, In Vitro Dissolution Testing, and In Vivo Bioequivalence Documentation'' (*http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070636.pdf*), (2) ''SUPAC–MR: Modified Release Solid Oral Dosage Forms Scale-Up and Post-Approval Changes: Chemistry, Manufacturing and Controls; In Vitro Dissolution Testing and In Vivo Bioequivalence Documentation'' (*http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070640.pdf*), and (3) ''SUPAC–SS: Nonsterile Semisolid Dosage Forms, Scale-Up and Post Approval Changes: Chemistry Manufacturing and Controls; In Vitro Release Testing and In Vivo Bioequivalence Documentation'' (*http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070930.pdf*).

As part of a greater effort, FDA is thoroughly reviewing the SUPAC guidance series to determine how these guidances fit with current manufacturing practices, including, but not limited to, risk-based assessment approaches and quality by design principles. These efforts will also be considered part of the finalization process for this guidance.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on manufacturing equipment. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: March 26, 2013.

Peter Lurie,

Acting Associate Commissioner for Policy and Planning.

[FR Doc. 2013–07432 Filed 3–29–13; 8:45 am]

BILLING CODE 4160–01–P