approval. In some cases, similar research is being conducted in different laboratories for the same medical countermeasure need. Participants will be encouraged to share experiences and join in collaborations to prevent duplication of research and avoid repetition of failed efforts and otherwise join in support of each other to attain shared goals and facilitate countermeasure development and approval.

3. Continuing Education—Areas of Focus

a. *GLP in high and maximum containment.*—This portion of the training will be a joint UTMB/FDA effort, with UTMB providing the course foundation and FDA offering the field inspector perspective. Lecture examples would include a GLP Refresher, Good Documentation practices, Internal GLP Audits, Equipment Validation and Calibration, and Effective SOPs. Lectures could be followed with practical exercises pointing out specific challenges in meeting GLP requirements that have been encountered in BSL–3 and BSL–4 studies conducted at UTMB.

b. *The ''Animal Rule.''*—FDA will provide an overview of the regulations for approval of new drugs and biologics based on evidence of effectiveness from studies in animals, including the status of FDA's draft document entitled, ''Guidance for Industry: Animal Models—Essential Elements to Address Efficacy Under the Animal Rule'' dated January 2009 (Draft Guidance) and the animal model qualification process.

c. *Animal welfare.*—This portion of the training will review animal welfare laws, policies guidelines and requirements, including lectures and discussions on the role of the veterinarian, determination of humane endpoints, and use of supportive care measures in BSL–4 studies.

d. *Telemetry.*—Use of telemetry for remote monitoring of routine clinical parameters, such as body temperature, heart rate, respiration rate, and blood pressure is a helpful and sometimes an essential tool for conducting studies in BSL–4 laboratories. An entire half-day will be devoted to teaching what is available and how to implement telemetry techniques into BSL–4 studies.

4. Dissemination of Successful Enhancements to the Regulatory Science and Regulation of Animal Rule Studies for Medical Countermeasure Development

UTMB and OCET will collaborate to incorporate any new FDA guidances and educational tools into the training program as new measures are developed (e.g., drug development tool guidance, updates to GLPs).

C. Eligibility Information

As work in regulatory science for medical countermeasure development progresses, OCET and UTMB anticipate additional collaboration through seminars and training programs, particularly in the areas of GLP in maximum and high biocontainment laboratories, training FDA field inspectors how to effectively conduct GLP inspections in a high or maximum biocontainment laboratories, and training laboratorians and regulators in how to work in high or maximum biocontainment laboratories. With the financial and scientific support from FDA, UTMB is uniquely qualified to undertake these activities, given its mandate as an educational and scientific institution, its high visibility as a pioneer in implementing GLP in maximum and high biocontainment laboratories, and its access to worldwide scientific and regulatory expertise. UTMB has demonstrated a GLP reporting structure and large animal in vivo GLP BSL–4 expertise. In addition, the FDA/UTMB training program will be accessible to researchers at all other university, government, and private organizations.

II. Award Information/Funds Available

A. Award Amount

Only one award will be made.

OCET anticipates providing in FY2012 up to $150,000 (total costs include direct and indirect costs) for one award subject to availability of funds in support of this project. The possibility of four additional years of support up to $600,000 of funding is contingent upon successful performance and the availability of funds.

B. Length of Support

The timeframe for this project is 5 years from the award date of the initial application.

III. Paper Application, Registration, and Submission Information

To submit a paper application in response to this FOA, applicants should first review the full announcement located at (*http://www.fda.gov/EmergencyPreparedness/MedicalCountermeasures/default.htm*). (FDA has verified the Web site addresses throughout this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**). Persons interested in applying for a grant may obtain an application at *http://grants2.nih.gov/grants/funding/phs398/phs398.html.* For all paper application submissions, the following steps are required:

- *Step 1:* Obtain a Dun and Bradstreet (DUNS) Number.
- *Step 2:* Register With Central Contractor Registration.
- *Step 3:* Register With Electronic Research Administration (eRA) Commons.

Steps 1 and 2, in detail, can be found at *http://www07.grants.gov/applicants/organization_registration.jsp.* Step 3, in detail, can be found at *https://commons.era.nih.gov/commons/registration/registrationInstructions.jsp.* After you have followed these steps, submit paper applications to: Gladys Melendez Bohler, Office of Acquisitions and Grants Services (HFA–500), 5630 Fishers Lane, Rm. 1078, Rockville, MD 20857.

Dated: June 12, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–14741 Filed 6–15–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0194]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Biosimilars User Fee Cover Sheet; Form FDA 3792

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by July 18, 2012.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–New and title ''Biosimilars User Fee Cover Sheet; Form FDA 3792''. Also include the FDA

docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Juanmanuel Vilela, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7651, *juanmanuel.vilela@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Biosimilars User Fee Cover Sheet; Form FDA 3792—(OMB Control Number 0910-New)

The March 23, 2010 Affordable Care Act contains a subtitle called the Biologics Price Competition and Innovation Act of 2009 (BPCI Act) that amends the Public Health Service Act (PHS Act) and other statutes to create an abbreviated approval pathway for biological products shown to be biosimilar to or interchangeable with an FDA-licensed reference biological product. Section 351(k) of the PHS Act, added by the BPCI Act, allows a company to submit an application for licensure of a biosimilar or interchangeable biological product. The BPCI Act also amends section 735 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 379g) to include 351(k) applications in the definition of ''human drug application'' for the purposes of the prescription drug user fee provisions. The authority conferred by the FD&C Act's prescription drug user fee provisions expires in September 2012. The BPCI Act directs FDA to develop recommendations for a biosimilar biological product user fee program for FYs 2013 through 2017. FDA's recommendations for a biosimilar biological product user fee program were submitted to Congress on January 13, 2012. If enacted into law, FDA's proposed biosimilar biological product user fee program would require FDA to assess and collect user fees for certain meetings concerning biosimilar biological product development (BPD meetings), investigational new drug applications (INDs) intended to support a biosimilar biological product application, and biosimilar biological product applications and supplements. Proposed Form FDA 3792, the Biosimilars User Fee Cover Sheet, requests the minimum necessary information to determine the amount of the fee required, and to account for and track user fees. The form would provide a cross-reference of the fees submitted for a submission with the actual submission by using a unique number tracking system. The information collected would be used by FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) to initiate the administrative screening of biosimilar biological product INDs, applications, and supplements, and to account for and track user fees associated with BPD meetings.

In the **Federal Register** of March 13, 2012 (77 FR 14809), FDA published a 60-day notice requesting public comment on the proposed collection of information, Form FDA 3792, the Biosimilar User Fee Cover Sheet. FDA received the following comments:

(Comment 1) Suggests FDA use the term ''Biosimilar Biological Product Licensing Application (BBLA)'' or ''Interchangeable Biosimilar Biological Product Application (IBLA)'' for a biosimilar application instead of Biologics License Application (BLA) to avoid confusion and provide greater clarity.

(Response) FDA notes the Biosimilar User Fee Cover Sheet serves a billing and collections purpose, and does not indicate FDA's position on reference terms. However, to maintain consistency throughout the document and avoid any confusion, FDA refers to a biologics license application submitted under section 351(k) of the Public Health Service Act as a ''351(k) application''. Under FDA's proposed biosimilar biological product user fee program, user fees would be assessed only for those 351(k) applications that fall within the scope of the defined term ''biosimilar biological product application.'' Accordingly, FDA has made changes to the Biosimilar User Fee Cover Sheet to clarify that Form 3792 need not be submitted for certain specified types of 351(k) applications. Additionally, to address the need for greater clarity, FDA has added definitions of several other key terms to the Biosimilar User Fee Cover Sheet.

(Comment 2) Requests FDA to ask for all available product names, including the product's code name in addition to trade and proper names, because the Biosimilar User Fee Cover Sheet should be consistent with Form FDA 1571. Further, requests FDA to amend the ''Product Name'' information field to ''Product Name(s).''

(Response) We agree that the Biosimilar User Fee Cover sheet should be consistent with Form 1571, where applicable. Accordingly, FDA amended the instructions to request proper name, trade or proprietary name, and code name, as applicable, and amended the ''Product Name'' information field to ''Product Name(s)''.

(Comment 3) Requests FDA to remove the question about whether the application requires clinical data, other than comparative bioavailability studies, for approval because this information does not affect the fee amount.

(Response) FDA notes this question applies only to fees for biosimilar biological product applications, and not to fees for biosimilar biological products in development. Under FDA's proposed biosimilar biological product user fee program, the fee amount for a biosimilar biological product application depends on whether clinical data with respect to safety or effectiveness are required. Specifically:

- A full fee is assessed for a biosimilar biological product application for which clinical data (other than comparative bioavailability studies) with respect to safety or effectiveness are required for approval;
- A half fee is assessed for a biosimilar biological product application for which clinical data (other than comparative bioavailability studies) with respect to safety or effectiveness are not required for approval;
- A half fee is assessed for a supplement for which clinical data (other than comparative bioavailability studies) with respect to safety or effectiveness are required for approval; and
- No fee is assessed for a supplement for which clinical data (other than comparative bioavailability studies) with respect to safety or effectiveness are not required for approval.

Therefore, FDA has retained the question on the Biosimilar User Fee Cover Sheet concerning whether clinical data are required because it requests information necessary to determine the fee amount for a biosimilar biological product application or supplement.

(Comment 4) Requests FDA to decline to require a patent certification as part of a 351(k) application.

(Response) FDA notes this comment is outside the scope of the proposed collection of information, Form FDA 3792, the Biosimilar User Fee Cover Sheet.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
FDA 3792	9	1	9	0.5 (30 minutes)	4.5

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

Respondents to this proposed collection of information would be manufacturers of biosimilar biological product candidates. Based on FDA's database system, there are an estimated 18 manufacturers that fall into this category. However, not all manufacturers will have submissions in a given year and some may have multiple submissions. FDA estimates 9 annual responses that include the following: 6 INDs or BPD meetings, 2 applications, and 1 supplement. The estimated hours per response are based on FDA's past experience with other submissions, which average 30 minutes.

Dated: June 12, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–14740 Filed 6–15–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

[Docket Number OIG–1301–N]

Solicitation of Information and Recommendations for Revising OIG's Provider Self-Disclosure Protocol

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice and Opportunity for Comment.

SUMMARY: This **Federal Register** notice informs the public that OIG: (1) Intends to update the Provider Self-Disclosure Protocol (63 FR 58399, October 30, 1998) and (2) solicits input from the public for OIG to consider in updating the Protocol.

DATES: To ensure consideration, public comments must be delivered to the address provided below by no later than 5 p.m. on August 17, 2012.

ADDRESSES: In commenting, please refer to file code OIG–1301–N. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of three ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific recommendations and proposals through the Federal eRulemaking Portal at *http://www.regulations.gov.*

2. *By regular, express, or overnight mail.* You may send written comments to the following address: Kenneth D. Kraft, Office of Inspector General, Department of Health and Human Services, Attention: OIG–1301–N, Room 5541B, Cohen Building, 330 Independence Avenue SW., Washington, DC 20201. Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By hand or courier.* If you prefer, you may deliver, by hand or courier, your written comments before the close of the comment period to Kenneth D. Kraft, Office of Inspector General, Department of Health and Human Services, Cohen Building, 330 Independence Avenue SW., Washington, DC 20201. Because access to the interior of the Cohen Building is not readily available to persons without Federal Government identification, commenters are encouraged to schedule their delivery with one of our staff at (202) 708–9848.

All submissions must include the agency name and docket number for this **Federal Register** document. All comments, including attachments and other supporting material received, are subject to public disclosure.

FOR FURTHER INFORMATION CONTACT: Kenneth D. Kraft, Department of Health and Human Services, Office of Inspector General, Office of External Affairs, at (202) 708–9848.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* All comments received before the end of the comment period are available for viewing by the public. All comments will be posted on *http://www.regulations.gov* after they have been received. Comments received timely will also be available for public inspection as they are received at Office of Inspector General, Department of Health and Human Services, Cohen Building, 330 Independence Avenue SW., Washington, DC 20201, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone (202) 708–9848.

Background: In 1998, OIG published the Provider Self-Disclosure Protocol (the Protocol) to establish a process for health care providers to disclose potential fraud involving the Federal health care programs. The Protocol provides guidance on how to investigate this conduct, quantify damages, and report the conduct to OIG to resolve the provider's liability exposure under OIG's civil money penalty (CMP) authorities. Over the past 14 years, we have resolved over 800 disclosures, resulting in recovering over $280 million to the Federal health care programs. Through our experience in resolving Protocol matters, we identified areas where additional guidance would be beneficial to the provider community and would improve the efficient resolution of Protocol matters. Specifically, we issued three Open Letters to Health Care Providers to address some of these issues. First, in 2006 we announced an initiative to encourage disclosure of conduct creating liability under OIG's anti-kickback and physician self-referral law CMP authorities. In 2008, we issued additional guidance and requirements for Protocol submissions to increase the efficiency of the Protocol, including new requirements for the initial submission and specific time commitments from the provider. This Open Letter also announced the presumption of not requiring a compliance agreement as part of settling a cooperative and complete disclosure. Finally, in 2009, we stated we would no longer accept disclosure of a matter into the Protocol that involved only liability under the physician self-referral law in the absence of a colorable anti-kickback violation. We also announced a minimum $50,000 settlement amount for kickback-related submissions.

After over a decade of experience in resolving Protocol disclosures, we are considering revising the Protocol to provide additional guidance. We are soliciting comments, recommendations, and other suggestions from concerned parties and organizations on how best to revise the Protocol to address relevant issues and to provide useful guidance to the health care industry.