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 these topics: (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.

Medical Devices: Recommended Glossary and Educational Outreach to Support Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use (OMB Control Number 0910–0553)—Extension

Section 502 of the Federal Food, Drug and Cosmetic Act (the FD&C Act) (21 U.S.C. 352), among other things, establishes requirements for the label or labeling of a medical device so that it is not misbranded. Section 351 of the Public Health Service Act (the PHS Act) (42 U.S.C. 262) establishes requirements that manufacturers of biological products must submit a license application for FDA review and approval prior to marketing a biological product for introduction into interstate commerce.

In the **Federal Register** of November 30, 2004 (69 FR 69606), FDA published a notice of availability of the guidance entitled "Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use." The guidance document provides guidance for the voluntary use of selected symbols in place of text in labeling. It provides the labeling guidance required for: (1) In vitro diagnostic devices (IVDs), intended for professional use under 21 CFR 809.10, FDA's labeling requirements for IVDs and (2) FDA's labeling requirements for biologics, including IVDs under 21 CFR parts 610 and 660. Under section 502(c) of the FD&C Act, a drug or device is misbranded, "* * *If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use."

The guidance document recommends that a glossary of terms accompany each IVD to define the symbols used on that device's labels and/or labeling. Furthermore, the guidance recommends an educational outreach effort to enhance the understanding of newly introduced symbols. Both the glossary and educational outreach information will help to ensure that IVD users will have enough general familiarity with the symbols used, as well as provide a quick reference for available materials, thereby further ensuring that such labeling satisfies the labeling requirements under section 502(c) of the FD&C Act and section 351 of the PHS Act.

The likely respondents for this collection of information are IVD manufacturers who plan to use the selected symbols in place of text on the labels and/or labeling of their IVDs.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN[1]

Section 502 of the FD&C Act/Section 351 of the PHS Act	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Glossary	689	1	689	4	2,756

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

The glossary activity is inclusive of both domestic and foreign IVD manufacturers. FDA receives submissions from approximately 689 IVD manufacturers annually. The number of hours per response for the glossary and educational outreach activities were derived from consultation with a trade association and FDA personnel. The 4-hour estimate for a glossary is based on the average time necessary for a manufacturer to modify the glossary for the specific symbols used in labels or labeling for the IVDs manufactured.

Dated: September 30, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–25008 Filed 10–4–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0161]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Export of Food and Drug Administration Regulated Products: Export Certificates

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 November 4, 2010.

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 0910–0498. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–

400B, Rockville, MD 20850, 301–796–3794, *Jonnalynn.Capezzuto@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.

Export of Food and Drug Administration Regulated Products: Export Certificates—(OMB Control Number 0910–0498)—Extension

In April 1996, a law entitled "The FDA Export Reform & Enhancement Act of 1996" (FDAERA) amended sections 801(e) and 802 of the act (21 U.S.C. 381(e) and 382). It was designed to ease restrictions on exportation of unapproved pharmaceuticals, biologics, and devices regulated by FDA. Section 801(e)(4) of the FDAERA provides that persons exporting certain FDA-regulated products may request FDA to certify that the products meet the requirements of 801(e) and 802 or other requirements of the act. This section of the law requires FDA to issue certification within 20 days of receipt of the request and to charge firms up to $175 for the certifications.

This new section of the act authorizes FDA to issue export certificates for regulated pharmaceuticals, biologics, and devices that are legally marketed in the United States, as well as for these same products that are not legally marketed but are acceptable to the importing country, as specified in sections 801(e) and 802 of the act. FDA has developed five types of certificates that satisfy the requirements of section 801(e)(4)(B) of the act: (1) Certificates to Foreign Governments, (2) Certificates of Exportability, (3) Certificates of a Pharmaceutical Product, (4) Non-Clinical Research Use Only Certificates, and (5) Certificates of Free Sale. Table 1 of this document lists the different certificates and details their use:

Type of Certificate	Use
"Supplementary Information Certificate to Foreign Government Requests" "Exporter's Certification Statement Certificate to Foreign Government" "Exporter's Certification Statement Certificate to Foreign Government (For Human Tissue Intended for Transplantation)"	For the export of products legally marketed in the United States
"Supplementary Information Certificate of Exportability Requests" "Exporter's Certification Statement Certificate of Exportability"	For the export of products not approved for marketing in the United States (unapproved products) that meet the requirements of sections 801(e) or 802 of the act
"Supplementary Information Certificate of a Pharmaceutical Product" "Exporter's Certification Statement Certificate of a Pharmaceutical Product"	Conforms to the format established by the World Health Organization and is intended for use by the importing country when the product in question is under consideration for a product license that will authorize its importation and sale or for renewal, extension, amending, or reviewing a license
"Supplementary Information Non-Clinical Research Use Only Certificate" "Exporter's Certification Statement (Non-Clinical Research Use Only)"	For the export of a non-clinical research use only product, material, or component that is not intended for human use which may be marketed in, and legally exported from the United States under the act
Certificate of Free Sale	For food, cosmetic products, and dietary supplements that may be legally marketed in the United States

FDA will continue to rely on self-certification by manufacturers for the first three types of certificates listed in table 1 of this document. Manufacturers are requested to self-certify that they are in compliance with all applicable requirements of the act, not only at the time that they submit their request to the appropriate center, but also at the time that they submit the certification to the foreign government.

The appropriate FDA centers will review product information submitted by firms in support of their certificate and any suspected case of fraud will be referred to FDA's Office of Criminal Investigations for followup. Making or submitting to FDA false statements on any documents may constitute violations of 18 U.S.C. 1001, with penalties including up to $250,000 in fines and up to 5 years imprisonment.

In the **Federal Register** of March 31, 2010 (75 FR 16137), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—TOTAL ESTIMATED ANNUAL REPORTING BURDEN[1]

FDA Center	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Center for Biologics Evaluation and Research	2,114	1	2,114	1	2,114
Center for Drug Evaluation and Research	5,251	1	5,251	2	10,502
Center for Devices and Radiological Health	6,463	1	6,463	2	12,926
Center for Veterinary Medicine	855	1	855	1	855

TABLE 1—TOTAL ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

FDA Center	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Center for Food Safety and Applied Nutrition (Three different product categories)					
	386	2	772	1.5	1,158
	247	47	11,609	2	23,218
	337	1	337	0.5	169
Total	15,653		27,401		50,942

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

Dated: September 30, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–25009 Filed 10–4–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0477]

Approval Pathway for Biosimilar and Interchangeable Biological Products; Public Hearing; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public hearing; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a 2-day public hearing to obtain input on specific issues and challenges associated with the implementation of the Biologics Price Competition and Innovation Act of 2009 (BPCI Act). The BPCI Act establishes an abbreviated approval pathway for biological products that are demonstrated to be "highly similar" (biosimilar) to, or "interchangeable" with, an FDA-licensed biological product. The purpose of this public hearing is to create a forum for interested stakeholders to provide input regarding the agency's implementation of the statute. FDA will take the information it obtains from the public hearing into account in its implementation of the BPCI Act.

DATES: The public hearing will be held November 2 and 3, 2010, from 8:30 a.m. to 4:30 p.m. Individuals who wish to present at the public hearing must register on or before October 11, 2010. Section III of this document provides attendance and registration information. Electronic or written comments will be accepted after the public hearing until December 31, 2010.

ADDRESSES: The public hearing will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Building 31, Rm. 1503, Silver Spring, MD 20993.

Submit electronic comments to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. Identify comments with the corresponding docket number found in brackets in the heading of this document.

Transcripts of the public hearing will be available for review at the Division of Dockets Management and on the Internet at *http://www.regulations.gov* approximately 30 days after the public hearing (see Section VI of this document).

A live webcast of this public hearing will be viewable at the following Web addresses on the days of the public hearing: *http://www.fda.gov/Drugs/NewsEvents/ucm221688.htm.* A video record of the public hearing will be available at the same Web addresses for 1 year.

FOR FURTHER INFORMATION CONTACT: Sandra J. Benton, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Ave., Bldg. 51, Rm. 6340, Silver Spring, MD 20993, 301–796–1042, FAX: 301–847–3529, *E-mail: biosimilarspublicmtg@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On March 23, 2010, President Obama signed into law the Patient Protection and Affordable Care Act (Affordable Care Act) (Pub. L. 111–148). The 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 (see sections 7001 through 7003 of the BPCI Act).

The objectives of the BPCI Act are conceptually similar to those of the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (commonly referred to as the "Hatch-Waxman Act"), which established abbreviated pathways for the approval of drug products under the Federal Food, Drug, and Cosmetic Act (FD&C Act). The BPCI Act aligns with FDA's longstanding policy of permitting appropriate reliance on what is already known about a drug, thereby saving time and resources and avoiding unnecessary duplication of human or animal testing. The implementation of an abbreviated approval pathway for biological products can present challenges given the scientific and technical complexities that may be associated with the larger and often more complex structure of biological products, as well as the processes by which such products are manufactured. Most biological products are produced in a living system such as a microorganism, or plant or animal cells, whereas small molecule drugs are typically manufactured through chemical synthesis.

Section 351(k) of the PHS Act (42 U.S.C. 262(k)), added by the BPCI Act, describes the general requirements for an application for a proposed biosimilar biological product and an application or a supplement for a proposed interchangeable biological product.

A biological product may be demonstrated to be "biosimilar" to a biological reference product based upon data derived from analytical studies, animal studies, and a clinical study or studies if the product is shown to be highly similar to the reference product, notwithstanding minor differences in clinically inactive components, and if there are no clinically meaningful differences between the biological product and the reference product in terms of safety, purity and potency.