information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202–395–6974, Attn: Desk Officer for the Administration for Children and Families.

Dated: March 7, 2012.

Steven M. Hanmer,

Reports Clearance, Officer; Office of Planning, Research and Evaluation.

[FR Doc. 2012–5951 Filed 3–12–12; 8:45 am]

BILLING CODE 4184–37–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0194]

Agency Information Collection Activities: Proposed Collection; 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 an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments concerning Form FDA 3792, entitled ''Biosimilars User Fee Cover Sheet.''

DATES: Submit written or electronic comments on the collection of information by May 14, 2012.

ADDRESSES: 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, Rm. 1061, Rockville, MD 20852. All comments should be identified with the 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: Under the 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 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 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) 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 fiscal years 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 and Center for Biologics Evaluation and Research 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.

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 nine annual responses that include the following: Six INDs or BPD meetings, two applications, and one supplement. The estimated hours per response are based on FDA's past experience with other submissions, and average 30 minutes.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Form	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
FDA 3792	9	1	9	0.5	4.5

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

Dated: March 7, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–6034 Filed 3–12–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0085]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Cooperative Manufacturing Arrangements for Licensed Biologics

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Cooperative Manufacturing Arrangements for Licensed Biologics'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Alla S. Mizrachi, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7726, *ila.mizrachi@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On August 10, 2011, the Agency submitted a proposed collection of information entitled ''Cooperative Manufacturing Arrangements for Licensed Biologics'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0629. The approval expires on February 28, 2015. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: March 6, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–6021 Filed 3–12–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–P–0527]

Determination That DURANEST (Etidocaine Hydrochloride) Injection, 0.5%, and Five Other DURANEST Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that the DURANEST (etidocaine hydrochloride) drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) that refer to these drug products if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Rachel Bressler, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6302, Silver Spring, MD 20993–0002, 301–796–4288.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

The drug products listed in the table in this document are no longer being marketed. DURANEST is indicated for infiltration anesthesia, peripheral nerve blocks (e.g., brachial plexus, intercostal retrobular, ulnar, inferior alveolar), and central nerve block (i.e., lumbar or caudal epidural blocks).

Application No.	Drug	Applicant	Initial approval date
NDA 17–751	DURANEST (epinephrine bitartrate; etidocaine hydrochloride) Injection 1%.	AstraZeneca Pharmaceutical	August 30, 1976.