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Determination That DURANEST (Etidocaine Hydrochloride) Injection, 0.5%, and Five Other DURANEST Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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

Application No.	Drug	Applicant	Initial approval date
Do.	DURANEST (epinephrine bitartrate; etidocaine hydrochloride) Injection 1.5%.	.....do	Do.
Do.	DURANEST (epinephrine; etidocaine hydrochloride) Injection 0.5%	.....do	Do.
Do.	DURANEST (etidocaine hydrochloride) Injection 0.5%	.....do	Do.
Do.	DURANEST (etidocaine hydrochloride) Injection 1%	.....do	Do.
NDA 21–384	DURANEST (epinephrine bitartrate; etidocaine hydrochloride) Injection 1.5%.	DENTSPLY Pharmaceutical	Do.

The drug products listed in the table in this document are currently listed in the ''Discontinued Drug Product List'' section of the Orange Book. Lachman Consultant Services, Inc. submitted a citizen petition dated September 25, 2008 (Docket No. FDA–2008–P–0527), under 21 CFR 10.30, requesting that the Agency determine whether DURANEST (etidocaine hydrochloride) Injection, 0.5% and 1%, were withdrawn from sale for reasons of safety or effectiveness. Although the citizen petition did not request a determination for the other DURANEST drug products listed in the table in this document, those drug products have also been discontinued. On our own initiative, we have also determined whether those products were withdrawn for safety or effectiveness reasons.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that the DURANEST drug products listed in the table in this document were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that the DURANEST drug products were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of the DURANEST drug products from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that the products were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the Agency will continue to list the DURANEST drug products listed in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to any of the DURANEST drug products listed in the table in this document may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: March 8, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–6039 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–2012–D–0022]

Draft Guidance for Industry on Direct-to-Consumer Television Advertisements—the Food and Drug Administration Amendments Act of 2007 Direct-to-Consumer Television Ad Pre-Dissemination Review Program; 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 ''Direct-to-Consumer Television Advertisements—FDAAA DTC Television Ad Pre-Dissemination Review Program.'' This draft guidance is intended to assist sponsors of human prescription drug products, including biological drug products, who are subject to the pre-dissemination review of television advertisements (TV ads) provision of the Federal Food, Drug, and Cosmetic Act (the FD&C Act). (The term ''pre-dissemination review'' is used throughout the guidance to refer to review under the FD&C Act, which is entitled ''Prereview of Television Advertisements.'') The draft guidance describes which TV ads FDA intends to make subject to this provision, explains how FDA will notify sponsors that an ad is subject to review under this provision, and describes the general and center-specific procedures sponsors should follow to submit their TV ads to FDA for pre-dissemination review in compliance with the FD&C Act. These proposed TV ads will be subject to a 45-calendar day review clock by FDA.

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 comments 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 14, 2012. Submit written comments on the proposed collection of information by May 14, 2012.

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 to the 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. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. 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: Regarding human prescription drugs: Marci Kiester, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 3368, Silver Spring, MD 20993–0002, 301–796–1200.

Regarding prescription human biological products: Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike,