canceled or superseded by another bulletin.

3. *Designation.* The names of the designated buildings are as follows:

Robert H. Jackson United States Courthouse
2 Niagara Square
Buffalo, NY 14202

Alto Lee Adams, Sr., United States Courthouse
United States Route 1
Fort Pierce, FL 34950

James F. Battin United States Courthouse
2601 2nd Avenue North
Billings, MT 59101

(Location at 315 North 26th Street shall no longer be designated as the James F. Battin U.S. Courthouse)

4. *Redesignation.* The former and new names of the redesignated buildings are as follows:

Former Name	*New Name*
Ariel Rios Federal Building 1200 Pennsylvania Avenue NW. Washington, DC 20004	William Jefferson Clinton Federal Building 1200 Pennsylvania Avenue NW. Washington, DC 20004
George Mahon Federal Building 200 East Wall Street Midland, TX 79701	George H.W. Bush and George W. Bush United States Courthouse and George Mahon Federal Building 200 East Wall Street Midland, TX 79701
Federal Office Building 8 200 C Street, SW. Washington, DC 20204	Thomas P. O'Neill, Jr., Federal Building 200 C Street, SW. Washington, DC 20204

5. *Who should we contact for further information regarding designation and redesignation of these Federal buildings*? U.S. General Services Administration, Public Buildings Service (PBS), 1800 F Street NW., Washington, DC 20405, telephone number: 202–501–1100.

Dan Tangherlini,
Acting Administrator of General Services.

[FR Doc. 2013–11247 Filed 5–10–13; 8:45 am]

BILLING CODE 6820–23–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Meeting of the Community Preventive Services Task Force (Task Force)

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting.

SUMMARY: The Centers for Disease Control and Prevention (CDC) announces the next meeting of the Community Preventive Services Task Force (Task Force). The Task Force is independent and nonfederal. Its members are nationally known leaders in public health practice, policy, and research, and are appointed by the CDC Director. The Task Force was convened in 1996 by the Department of Health and Human Services (HHS) to assess the effectiveness of community, environmental, population, and healthcare system interventions in public health and health promotion. During this meeting, the Task Force will consider the findings of systematic reviews and issue findings and recommendations to help inform decision making about policy, practice, and research in a wide range of U.S. settings. The Task Force's recommendations, along with the systematic reviews of the scientific evidence on which they are based, are compiled in the *Guide to Community Preventive Services (Community Guide).*

DATES: The meeting will be held on Wednesday, June 19, 2013 from 8:30 a.m. to 5:30 p.m., EDT and Thursday, June 20, 2013 from 8:30 a.m. to 1:00 p.m. EDT.

Logistics: The Task Force Meeting will be held at the Emory Conference Center at 1615 Clifton Road Atlanta, GA 30329. Information regarding logistics will be available Wednesday, May 22, 2013 on the Community Guide Web site (*www.thecommunityguide.org*).

FOR FURTHER INFORMATION CONTACT: Andrea Baeder, The Community Guide Branch, Epidemiology and Analysis Program Office, Office of Surveillance, Epidemiology, and Laboratory Services, Centers for Disease Control and Prevention, 1600 Clifton Road, MS–E–69, Atlanta, Georgia 30333, phone: (404) 498–6876, email: *CPSTF@cdc.gov*.

Purpose: The purpose of the meeting is for the Task Force to consider the findings of systematic reviews and issue findings and recommendations to help inform decision making about policy, practice, and research in a wide range of U.S. settings.

Matters to be discussed: Matters to be discussed: cancer prevention and control, cardiovascular disease prevention and control, diabetes prevention and control, motor vehicle-related injury prevention, improving oral health, promoting physical activity, promoting health equity, and reducing tobacco use and secondhand smoke exposure.

Meeting Accessibility: This meeting is open to the public, limited only by space availability.

Dated: May 6, 2013.

Tanja Popovic,

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

[FR Doc. 2013–11242 Filed 5–10–13; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–1131]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; New Animal Drug Applications and Supporting Regulations and Form FDA 356V

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 June 12, 2013.

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 0910–0032. 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.

Presubmission Conferences, New Animal Drug Applications and Supporting Regulations and Guidance #152, and Form FDA 356V—21 CFR 514.5, 514.1, 514.4, and 514.8 (OMB Control Number 0910–0032)—Extension

Under section 512(b)(3) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360b(b)(3)), any person intending to file a new animal drug application (NADA) or supplemental NADA or a request for an investigational exemption under section 512(j) of the FD&C Act is entitled to one or more conferences with FDA to reach an agreement acceptable to FDA establishing a submission or investigational requirement. FDA and industry have found that these meetings have increased the efficiency of the drug development and drug review processes.

Section 514.5 of Title 21 of the Code of Federal Regulations describes the procedures for requesting, conducting, and documenting presubmission conferences. Section 514.5(b) describes the information that must be included in a letter submitted by a potential applicant requesting a presubmission conference, including a proposed agenda and a list of expected participants. Section 514.5(d) describes the information that must be provided by the potential applicant to FDA at least 30 days prior to a presubmission conference. This information includes a detailed agenda, a copy of any materials to be presented at the conference, a list of proposed indications and, if available, a copy of the proposed labeling for the product under consideration, and a copy of any background material that provides scientific rationale to support the potential applicant's position on issues listed in the agenda for the conference. Section 514.5(f) discusses the content of the memorandum of conference that will be prepared by FDA and gives the potential applicant an opportunity to seek correction to or clarification of the memorandum.

Under section 512(b)(1) of the FD&C Act, any person may file a NADA seeking approval to legally market a new animal drug. Section 512(b)(1) sets forth the information required to be submitted in a NADA. FDA allows applicants to submit a complete NADA or to submit information in support of a NADA for phased review followed by submission of an administrative NADA when FDA finds all the applicable technical sections are complete.

Section 514.1 of Title 21 of the Code of Federal Regulations interprets section 512(b)(1) of the FD&C Act and further describes the information that must be submitted as part of a NADA and the manner and form in which the NADA must be assembled and submitted. The application must include safety and effectiveness data, proposed labeling, product manufacturing information, and where necessary, complete information on food safety (including microbial food safety) and any methods used to determine residues of drug chemicals in edible tissue from food producing animals. Guidance #152 outlines a risk assessment approach for evaluating the microbial food safety of antimicrobial new animal drugs. FDA requests that an applicant accompany NADAs, supplemental NADAs, and requests for phased review of data to support NADAs, with the Form FDA 356V to ensure efficient and accurate processing of information to support new animal drug approval.

In the **Federal Register** of November 20, 2012, (77 FR 69630), 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—NADAs—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section/FDA form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
514.5(b), (d), (f) Requesting presubmission conferences	169	0.41	69	50	3,450
514.1 and 514.6 Applications and amended applications	169	0.07	12	212	2,544
514.8(b) Manufacturing changes to an approved application	169	2.22	375	35	13,125
514.8(c)(1) Labeling and other changes to an approved application	169	0.06	10	71	710
514.8(c)(2) and (3) Labeling and other changes to an approved application	169	0.72	121	20	2,420
514.11 Submission of data, studies and other information	169	0.08	14	1	14
558.5(i) Requirements for liquid medicated feed	169	0.01	1.7	5	8.5
514.1(b)(8) and 514.8(c)(1) [2] Evidence to establish safety and effectiveness	169	0.15	25	90	2,250
Form FDA 356V	169	4.37	739	5	3,695
Total					28,217

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

[2] NADAs and supplements regarding antimicrobial animal drugs that use a recommended approach to assessing antimicrobial concerns as part of the overall preapproval safety evaluation.

Based on the number of sponsors subject to animal drug user fees, FDA estimates that there was an average of 169 annual respondents during the 5 fiscal years, from October 1, 2008, through September 30, 2012, on which

these estimates were made. We use this estimate consistently throughout the table and calculate the ''total annual responses'' by multiplying the number of responses per respondent by the number of respondents.

Dated: May 7, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–11273 Filed 5–10–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–P–1000]

Determination That REV–EYES (Dapiprazole Hydrochloride Ophthalmic Solution), 0.5%, Was 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 REV–EYES (dapiprazole hydrochloride ophthalmic solution), 0.5%, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for dapiprazole hydrochloride ophthalmic solution, 0.5%, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: David E. Markert, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6248, Silver Spring, MD 20993–0002, 301–796–3602.

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 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.

REV–EYES (dapiprazole hydrochloride ophthalmic solution), 0.5%, is the subject of NDA 19–849, held by Angelini Pharmaceuticals Inc., and initially approved on December 31, 1990. REV–EYES is indicated for the treatment of iatrogenically induced mydriasis produced by adrenergic (phenylephrine) or parasympatholytic (tropicamide) agents.

REV–EYES (dapiprazole hydrochloride ophthalmic solution), 0.5%, is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

CUSTOpharm, Inc., submitted a citizen petition dated September 11, 2012 (Docket No. FDA–2012–P–1000), under 21 CFR 10.30, requesting that the Agency determine whether REV–EYES (dapiprazole hydrochloride ophthalmic solution), 0.5%, was withdrawn from sale for reasons of safety or effectiveness.

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 REV–EYES (dapiprazole hydrochloride ophthalmic solution), 0.5%, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that REV–EYES (dapiprazole hydrochloride ophthalmic solution), 0.5%, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of REV–EYES (dapiprazole hydrochloride ophthalmic solution). 0.5%. from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list REV–EYES (dapiprazole hydrochloride ophthalmic solution), 0.5%, 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 REV–EYES (dapiprazole hydrochloride ophthalmic solution), 0.5%, 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 this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: May 8, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–11285 Filed 5–10–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0677]

Dental Products Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Dental Products Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on July 18th, 2013, from 8 a.m. to 2:30 p.m.

Location: Hilton Washington DC North/Gaithersburg, Salons A, B and C, 620 Perry Pkwy., Gaithersburg, MD,