

III. Marketing Policy

Under § 330.14(h), any sunscreen product containing drometrizole trisiloxane may not be marketed as an OTC drug in the United States at this time unless it is the subject of an approved new drug application or abbreviated new drug application.

IV. References

The following references are on display in the Division of Dockets Management (see **ADDRESSES**) under Docket No. FDA-2003-N-0196 and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Redacted TEA for drometrizole trisiloxane submitted by L'Oreal USA Products, Inc., dated January 21, 2009.

2. FDA's evaluation of the TEA for drometrizole trisiloxane.

Dated: May 25, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010-13001 Filed 6-1-10; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0001]

Cardiovascular and Renal Drugs 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: Cardiovascular and Renal Drugs 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 28, 2010, from 8 a.m. to 5 p.m.

Location: The Marriott Inn and Conference Center, University of Maryland University College, 3501 University Blvd. East, Adelphi, MD. The conference center telephone number is 301-985-7300.

Contact Person: Elaine Ferguson, c/o Christine Shipe, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2419, Silver Spring, MD 20993-0002, 301-796-9001, FAX: 301-847-8532, e-mail:

elaine.ferguson@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512533. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On July 28, 2010, the committee will discuss new drug application (NDA) 22-433, ticagrelor tablets, 90 milligrams, manufactured by AstraZeneca LP, for the proposed indication for use in acute coronary syndrome (including heart attacks and any of a group of signs and symptoms, such as chest pain or shortness of breath, that are consistent with blockages in the blood vessels that supply the heart).

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before July 14, 2010. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before July 6, 2010. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public

hearing session. The contact person will notify interested persons regarding their request to speak by July 7, 2010.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Elaine Ferguson at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: May 27, 2010.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2010-13141 Filed 6-1-10; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Privacy Act of 1974; CMS Computer Match No. 2010-03, HHS Computer Match No. 1003, SSA Computer Match No. 1048, IRS Project No. 241

AGENCY: Department of Health and Human Services (HHS), Centers for Medicare & Medicaid Services (CMS).

ACTION: Notice of renewal of an existing computer matching program (CMP) that has an expiration date of June 30, 2010.

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, as amended, this notice announces the renewal of an existing CMP between CMS, the Internal Revenue Service (IRS), and the Social Security Administration (SSA). We have provided information about the matching program in the **SUPPLEMENTARY INFORMATION** section below. The Privacy Act provides an opportunity for interested persons to comment on the matching program. We may defer implementation of this matching program if we receive comments that persuade us to defer

implementation. See "Effective Dates" section below for comment period.

DATES: *Effective Dates:* CMS filed a report of the Computer Matching Program (CMP) with the Chair of the House Committee on Oversight and Government Reform, the Chair of the Senate Committee on Homeland Security and Governmental Affairs, and the Acting Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) on May 19, 2010. We will not disclose any information under a matching agreement until 40 days after filing a report to OMB and Congress or 30 days after publication in the **Federal Register** whichever is later.

ADDRESSES: The public should address comments to: Walter Stone, CMS Privacy Officer, Division of Information Security & Privacy Management, Enterprise Architecture and Strategy Group, Office of Information Services (OIS), CMS, Mail stop N1-24-08, 7500 Security Boulevard, Baltimore, Maryland 21244-1850. Comments received will be available for review at this location, by appointment, during regular business hours, Monday through Friday from 9 a.m. to 3 p.m., eastern daylight time.

FOR FURTHER INFORMATION CONTACT: John Albert, Technical Advisor, Division of Medicare Benefits Coordination, Financial Services Group, Office of Financial Management, CMS, Mail stop C3-14-16, 7500 Security Boulevard, Baltimore, Maryland 21244-1850. The telephone number is (410) 786-7457, or e-mail at John.Albert@cms.hhs.gov.

SUPPLEMENTARY INFORMATION:

Description of the Matching Program

A. General

The Computer Matching and Privacy Protection Act of 1988 (Pub. L. 100-503) amended the Privacy Act (5 U.S.C. 552a) by describing the manner in which computer matching involving Federal agencies could be performed and adding certain protections for individuals applying for and receiving Federal benefits. Section 7201 of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101-508) further amended the Privacy Act regarding protections for such individuals. The Privacy Act, as amended, regulates the use of computer matching by Federal agencies when records in a system of records are matched with other Federal, State, or local government records. It requires Federal agencies involved in computer matching programs to:

- Negotiate written agreements with the other agencies participating in the matching programs;
- Obtain the Data Integrity Board approval of the match agreements;
- Furnish detailed reports about matching programs to Congress and OMB;
- Notify applicants and beneficiaries that the records are subject to matching; and
- Verify match findings before reducing, suspending, terminating, or denying an individual's benefits or payments.

B. CMS Computer Matches Subject to the Privacy Act

CMS has taken action to ensure that all CMPs that this Agency participates in comply with the requirements of the Privacy Act of 1974, as amended.

Dated: May 21, 2010.

Michelle Snyder,

Deputy Chief Operating Officer, Centers for Medicare & Medicaid Services.

CMS Computer Match No. 2010-03
HHS Computer Match No. 1003
SSA Computer Match No. 1048
IRS Project No. 241

NAME:

"Medicare Secondary Payer (MSP) Program".

SECURITY CLASSIFICATION:

Level Three Privacy Act Sensitive.

PARTICIPATING AGENCIES:

Internal Revenue Service (IRS), Social Security Administration (SSA), and the Centers for Medicare & Medicaid Services (CMS).

AUTHORITY FOR CONDUCTING MATCHING PROGRAM:

This Matching Agreement between IRS, SSA and CMS is executed pursuant to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, (as amended by Pub. L. 100-503, the Computer Matching and Privacy Protection Act (CMPPA) of 1988), the Office of Management and Budget (OMB) Circular A-130, titled "Management of Federal Information Resources" at 61 FR 6428-6435 (February 20, 1996), and OMB guidelines pertaining to computer matching at 54 FR 25818 (June 19, 1989).

This agreement implements the information matching provisions of § 6103(l)(12) of the Internal Revenue Code (IRC) (26 U.S.C 6103(1)(12)), and 1862(b)(5) of the Social Security Act (42 U.S.C. 1395y(b)(5)).

PURPOSE(S) OF THE MATCHING PROGRAM:

The purpose of this agreement is to establish the conditions under which:

- (1) IRS agrees to disclose return

information relating to taxpayer identity to SSA, and (2) SSA agrees to disclose return information relating to beneficiary and employer identity, commingled with information disclosed by the IRS, to CMS. These disclosures will provide CMS with information to determine the extent to which any Medicare beneficiary is covered under any Group Health Plan (GHP).

CATEGORIES OF RECORDS AND INDIVIDUALS COVERED BY THE MATCH:

IRS will disclose taxpayer identity information from the CADE (Customer Account Data Engine) Individual Master File (IMF), Treasury/IRS 24.030, published at 73 FR 13304 (March 12, 2008), and maintained at the Martinsburg Computing Center in Martinsburg, West Virginia. This file includes millions of records of taxpayers who have filed Federal Individual Income Tax Returns. IRS established Project 241, IMF/Medicare Beneficiary Match to facilitate this matching program.

SSA will extract identifying information of Medicare beneficiaries from the Master Beneficiary Record (MBR), SSA/OSR 60-0090, published at 71 FR. 1826 (January 11, 2006) and maintained at the National Computer Center (NCC) in Baltimore, MD. This file includes records of individuals who have received and are receiving benefits under the Social Security Act. SSA will extract employer identity information from the Earnings Recording and Self-employment Income System, SSA/OSR 60-0059, referred to as the Master Earnings File (MEF) published at 71 FR. 1819 (January 11, 2006) and maintained at the NCC. This file contains earnings records of individuals including identifying information of their employees. SSA will also extract employer name and address from the Employer Identification File (EIF).

CMS will utilize a database, Medicare Advantage Prescription Drug System (MARx) CMS System No. 09-70-4001, published at 70 FR 60530 (October 18, 2005), maintained at the CMS Data Center, located in Baltimore, Maryland, of the GHP information received from employers containing verified instances of employment and GHP coverage for Medicare beneficiaries and Medicare-eligible spouses identified from the IMF, EIF, and MEF extracts.

CMS will match GHP information against the Medicare Multi Carrier Claims System (MCS) (formerly known as Carrier Medicare Claims Records), CMS System No. 09-70-0501, published at 71 FR. 64968 (November 6, 2006), maintained at the CMS Data Center, located in Baltimore, Maryland.

These files contain information received from employers containing verified instances of employment and GHP coverage for Medicare beneficiaries and Medicare-eligible spouses identified from the IMF, EIF, and MEF extracts.

CMS will match GHP information against the Fiscal Intermediary Shared System (FISS) (formerly known as Intermediary Medicare Claims Records), CMS System No. 09-70-0503, published at 71 FR 64961 (November 6, 2006), maintained at the CMS Data Center, located in Baltimore, Maryland. This file contains information or records needed to properly process and pay Medicare benefits to, or on behalf of, eligible individuals. CMS accesses this file upon receiving a claim for payment.

CMS will match GHP information against the Common Working File (CWF), CMS System No. 09-70-0526, published at 71 FR 64955 (November 6, 2006), which is the repository data base for all current hospital and medical coverage MSP information, maintained at the CMS Data Center, located in Baltimore, Maryland. These files contain information or records needed to properly process and pay medical insurance benefits to, or on behalf of, entitled beneficiaries who have submitted claims for Supplementary Medical Insurance Benefits (Medicare Part B). CMS accesses this file upon receiving a claim for payment.

CMS will match GHP information against the National Claims History (NCH), which is contained in the National Claims History File, CMS System No. 09-70-0558, published at 71 FR 67137 (November 20, 2006), maintained at the CMS Data Center, located in Baltimore, Maryland. NCH contains records needed to facilitate obtaining Medicare utilization review data that will be useful for studies of the operation and effectiveness of the Medicare program.

INCLUSIVE DATES OF THE MATCH:

The Matching Program shall become effective 40 days after the report of the Matching Program is sent to OMB and Congress, or 30 days after publication in the **Federal Register**, which ever is later. The matching program will continue for 18 months from the effective date and may be extended for an additional 12 months thereafter, if certain conditions are met.

[FR Doc. 2010-13000 Filed 6-1-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Commission on Childhood Vaccines; Request for Nominations for Voting Members

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) is requesting nominations to fill three vacancies on the Advisory Commission on Childhood Vaccines (ACCV). The ACCV was established by Title XXI of the Public Health Service Act (the Act), as enacted by Public Law (Pub. L.) 99-660 and as subsequently amended, advises the Secretary of Health and Human Services (the Secretary) on issues related to implementation of the National Vaccine Injury Compensation Program (VICP).

DATES: The agency must receive nominations on or before July 2, 2010.

ADDRESSES: All nominations are to be submitted to the Director, Division of Vaccine Injury Compensation, Healthcare Systems Bureau (HSB), HRSA, Parklawn Building, Room 11C-26, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: Ms. Andrea Herzog, Principal Staff Liaison, Policy Analysis Branch, Division of Vaccine Injury Compensation, HSB, HRSA at (301) 443-6634 or e-mail: aherzog@hrsa.gov.

SUPPLEMENTARY INFORMATION: Under the authorities that established the ACCV, the Federal Advisory Committee Act of October 6, 1972 (Pub. L. 92-463) and section 2119 of the Act, 42 U.S.C. 300aa-19, as added by Pub. L. 99-660 and amended, HRSA is requesting nominations for three voting members of the ACCV.

The ACCV advises the Secretary on the implementation of the VICP. The activities of the ACCV include: Recommending changes in the Vaccine Injury Table at its own initiative or as the result of the filing of a petition; advising the Secretary in implementing section 2127 regarding the need for childhood vaccination products that result in fewer or no significant adverse reactions; surveying Federal, State, and local programs and activities related to gathering information on injuries associated with the administration of childhood vaccines, including the adverse reaction reporting requirements

of section 2125(b); advising the Secretary on the methods of obtaining, compiling, publishing, and using credible data related to the frequency and severity of adverse reactions associated with childhood vaccines; consulting on the development or revision of the Vaccine Information Statements and recommending to the Director of the National Vaccine Program that vaccine safety research be conducted on various vaccine injuries.

The ACCV consists of nine voting members appointed by the Secretary as follows: (1) Three health professionals, who are not employees of the United States Government and have expertise in the health care of children, and the epidemiology, etiology, and prevention of childhood diseases, and the adverse reactions associated with vaccines, at least two shall be pediatricians; (2) three members from the general public, at least two shall be legal representatives (parents or guardians) of children who have suffered a vaccine-related injury or death; and (3) three attorneys, at least one shall be an attorney whose specialty includes representation of persons who have suffered a vaccine-related injury or death, and one shall be an attorney whose specialty includes representation of vaccine manufacturers. In addition, the Director of the National Institutes of Health, the Assistant Secretary for Health, the Director of the Centers for Disease Control and Prevention, and the Commissioner of the Food and Drug Administration (or the designees of such officials) serve as nonvoting ex officio members.

Specifically, HRSA is requesting nominations for three voting members of the ACCV representing: (1) A health professional, who has expertise in the health care of children; and the epidemiology, etiology, and prevention of childhood diseases; (2) an attorney whose specialty includes representation of persons who have suffered a vaccine-related injury or death; and (3) a member of the general public who is the legal representative (parents or guardians) of a child who has suffered a vaccine related injury or death. Nominees will be invited to serve a 3-year term beginning January 1, 2011, and ending December 31, 2014.

Interested persons may nominate one or more qualified persons for membership on the ACCV. Nominations shall state that the nominee is willing to serve as a member of the ACCV and appears to have no conflict of interest that would preclude ACCV membership. Potential candidates will be asked to provide detailed information concerning consultancies, research grants, or contracts to permit evaluation