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:

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

This matching program meets the requirements of the Privacy Act of 1974, as amended.

Dated: August 14, 2013.

Michelle Snyder,

Chief Operating Officer, Centers for Medicare & Medicaid Services.

CMS Computer Match No. 2013–10; HHS Computer Match No. 1310

Name: ''Computer Matching Agreement between the Centers for Medicare & Medicaid Services and the Department of Homeland Security, United States Citizenship and Immigration Services, for the Verification of United States Citizenship and Immigration Status Data for Eligibility Determinations''.

Security Classification: Unclassified.

Participating Agencies: Department of Health and Human Services (HHS), Centers for Medicare & Medicaid Services (CMS), and Department of Homeland Security (DHS), United States Citizenship and Immigration Services (USCIS).

Authority for Conducting Matching Program: Sections 1411 and 1413 of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) (collectively, the ACA) require the Secretary of HHS to establish a program for determining eligibility for certain Insurance Affordability Programs and certifications of Exemption; in addition, these sections authorize use of secure, electronic interfaces and an on-line system for the verification of data and information related to Eligibility Determinations.

Purpose(s) of the Matching Program: The purpose of the Computer Matching Agreement is to establish the terms, conditions, safeguards, and procedures under which USCIS will provide records, information, or data to CMS. CMS will access USCIS data needed to make Eligibility Determinations in its capacity as a Federally-facilitated Exchange, and Administering Entities (state agencies that administer Medicaid or the Children's Health Insurance Program, and State-based Exchanges) will receive the results of verifications using USCIS data accessed through the CMS Data Services Hub to make Eligibility Determinations. Eligibility Determinations include initial determinations made upon application, renewals, annual or periodic redeterminations, and appeals.

Data will be matched by CMS for the purpose of Eligibility Determinations enrollment in Insurance Affordability Programs and Eligibility Determinations for Exemptions. Specifically, USCIS will provide CMS with electronic access to immigrant, nonimmigrant, and naturalized or derived citizen status information contained within or accessed by the USCIS Verification Information System. Access to this information will assist with verification whether an applicant is lawfully present, a qualified non-citizen, a naturalized or derived citizen, and whether the 5 year bar applies and has been met in order to determine eligibility for the previously mentioned programs.

Description of Records To Be Used In the Matching Program: The matching program will be conducted with data maintained by CMS in the Health Insurance Exchanges (HIX) Program, CMS System No. 09–70–0560, as amended. The system is described in System of Records Notices (SORNs) published at 78 FR 8538 (Feb. 6, 2013) and 78 FR 32256 (May 29, 2013).

The matching program will also be conducted with data maintained by DHS in the Systematic Alien Verification for Entitlements (SAVE) System of Records Notice (SAVE SORN): DHS/USCIS–004 Systematic Alien Verification for Entitlements Program System of Records Notice, 77 FR 47415 (August 8, 2012).

Inclusive Dates of the Match: The CMP will become effective no sooner than 40 days after the report of the matching program is sent to OMB and Congress, or 30 days after publication in the **Federal Register**, whichever 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. 2013–20173 Filed 8–16–13; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0924]

Determination That LIDEX (fluocinonide) Cream and LIDEX–E (fluocinonide) Cream and Nine Other 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 drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to continue to approve ANDAs that refer to the products as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Mark Geanacopoulos, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6206, Silver Spring, MD 20993–0002, 301–796–6925.

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 approved under an ANDA procedure. ANDA sponsors 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. Sponsors of ANDAs 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 generally known as the ''Orange Book.'' Under FDA regulations, a drug is 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).

Under § 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) Before an ANDA that refers to that listed drug may be approved; (2) whenever a listed drug is voluntarily withdrawn from sale and ANDAs that refer to the listed drug have been approved; and (3) when a person petitions for such a determination under 21 CFR 10.25(a) and 10.30. Section 314.161(d) provides that if FDA determines that a listed drug was withdrawn from sale for safety or effectiveness reasons, the Agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

FDA has become aware that the drug products listed in the table in this document are no longer being marketed.

Application No.	Drug	Applicant
NDA 016908	LIDEX (fluocinonide) Cream; Topical, 0.05%,	Medicis Pharmaceutical Corp., 7720 North Dobson Rd., Scottsdale, AZ 85256.
Do.	LIDEX–E (fluocinonide) Cream; Topical, 0.05%	Do.
NDA 018181	MYCELEX (clotrimazole) Solution; Topical, 1%	Bayer Health Care, 100 Bayer Rd., Pittsburgh, PA 15205.
NDA 018713	MYCELEX (clotrimazole) Lozenge; Oral, 10 milligrans (mg)	Do.
NDA 019510	PEPCID (famotidine) Injection, 10 mg/milliliter (mL)	Merck Research Laboratories, Inc., 770 Sumneytown Pike, West Point, PA 19486.
Do.	PEPCID PRESERVATIVE FREE (famotidine) Injection, 10 mg/mL.	Do.
NDA 020249	PEPCID PRESERVATIVE FREE IN PLASTIC CONTAINER (famotidine) Injection, 0.4 mg/mL.	Do.
NDA 021065	FEMHRT (ethinyl estradiol; norethindrone acetate) Tablet; Oral, 0.005 mg/1 mg.	Warner Chilcott LLC, 1 Grand Canal Sq., Docklands, Dublin 2, Ireland.
NDA 050763	MITOZYTREX (mitomycin) Injection, 5 mg/vial	SuperGen, Inc., 4140 Dublin Blvd., Suite 200, Dublin, CA 94568.
ANDA 086031	ISOSORBIDE DINITRATE (isosorbide dinitrate) Tablet; Sublingual, 5 mg.	Watson Laboratories, 577 Chipeta Way, Salt Lake City, UT 84108.
ANDA 086033	ISOSORBIDE DINITRATE (isosorbide dinitrate) Tablet; Sublingual, 2.5 mg.	Do.

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the Agency will continue to list the drug products listed in this document in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

Approved ANDAs that refer to the NDAs and ANDAs listed in this document are unaffected by the discontinued marketing of the products subject to those NDAs and ANDAs. Additional ANDAs that refer to these products may also be approved by the Agency if they comply with relevant legal and regulatory requirements. 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: August 13, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–20086 Filed 8–16–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2000–D–0187 (formerly Docket No. 2000D–1267)]

Guidance for Industry: Recommendations for Donor Questioning, Deferral, Reentry, and Product Management To Reduce the Risk of Transfusion-Transmitted Malaria; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Guidance for Industry: Recommendations for Donor Questioning, Deferral, Reentry and Product Management to Reduce the Risk of Transfusion-Transmitted Malaria'' dated August 2013. The guidance document provides blood establishments that collect blood and blood components with recommendations for questioning and deferring donors of blood and blood components, allowing their reentry, and product management to reduce the risk of transfusion-transmitted malaria. This guidance finalizes the draft guidance of the same title dated June 2012, and supersedes the FDA memorandum to all registered blood establishments entitled ''Recommendations for Deferral of Donors for Malaria Risk'' dated July 26, 1994. The recommendations contained in the guidance are not applicable to donors of Source Plasma.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance 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 the 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