IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/ScienceResearch/SpecialTopics/Nanotechnology/default.htm* or *http://www.regulations.gov.* Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

Dated: June 23, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–15033 Filed 6–26–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–E–0038]

Determination of Regulatory Review Period for Purposes of Patent Extension; VICTRELIS

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for VICTRELIS and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov.* Submit written petitions (two copies are required) and written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit petitions electronically to *http://www.regulations.gov* at Docket No. FDA–2013–S–0610.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Management, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6257, Silver Spring, MD 20993–0002, 301–796–7900.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product VICTRELIS (boceprevir). VICTRELIS is indicated for treatment of chronic hepatitis C genotype 1 infection, in combination with peginterferon alfa and ribavirin in adult patients with compensated liver disease, including cirrhosis, who are previously untreated or who have failed previous interferon and ribavirin therapy. Subsequent to this approval, the USPTO received a patent term restoration application for VICTRELIS (U.S. Patent No. RE43298) from Schering Corporation and Dendreon Corporation, and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated July 9, 2012, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of VICTRELIS represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for VICTRELIS is 2,160 days. Of this time, 1,980 days occurred during the testing phase of the regulatory review period, while 180 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(i)) became effective:* June 15, 2005. The applicant claims June 18, 2005, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was June 15, 2005, which was the date the applicant was informed that they could proceed with their proposed clinical investigations.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* November 15, 2010. FDA has verified the applicant's claim that the new drug application (NDA) for VICTRELIS (NDA 202–258) was submitted on November 15, 2010.

3. *The date the application was approved:* May 13, 2011. FDA has verified the applicant's claim that NDA 202–258 was approved on May 13, 2011.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,032 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments and ask for a redetermination by August 26, 2014. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by December 24, 2014. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments and written or electronic petitions. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. If you submit a written petition, two copies are required. A petition submitted electronically must be submitted to *http://www.regulations.gov,* Docket No. FDA–2013–S–0610. Comments and petitions that have not been made publicly

available on *http://www.regulations.gov* may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 23, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–15021 Filed 6–26–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0421]

Privacy Act of 1974; System of Records Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; changes to systems of records notices.

SUMMARY: In accordance with the requirements of the Privacy Act of 1974 (the Privacy Act) and the Food and Drug Administration's (FDA) regulations for the protection of privacy, FDA is deleting four system of records notices (SORNs) from its existing inventory of SORNs and adding routine uses to the remaining SORNs. The systems related to the SORNs that are being deleted are no longer in use by FDA. The additional routine uses are for standard disclosures common to systems across the government. They allow disclosure to other Federal Agencies and contractors as needed to respond to a breach of system security or confidentiality, to contractors or other external individuals performing work for FDA that requires access to Agency records subject to the Privacy Act, to Federal record keeping authorities for the purpose of records management oversight, to appropriate public authorities when a record indicates a potential violation of law, and to the U.S. Department of Justice (DOJ) for guidance on Freedom of Information Act issues. FDA will require that all of these recipients comply with the requirements of the Privacy Act. The added routine uses will be inserted in each existing system notice and will be included in future FDA SORNs.

DATES: This notice will be effective on June 27, 2014, with the exception of the new and altered routine uses. Those routine uses will become effective on August 11, 2014. Submit either electronic or written comments by August 11, 2014.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2014–N–0421, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- *Mail/Hand delivery/Courier (for paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA–2014–N–0421 for this notice. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number(s), found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Frederick Sadler or Cullen Cowley, Division of Freedom of Information, Food and Drug Administration, 12420 Parklawn Dr., Rm. 1050, Rockville, MD 20857, 301–796–3900.

SUPPLEMENTARY INFORMATION:

I. Deleted System of Records Notices

FDA is deleting the following SORNs because the record systems are no longer in use.

1. Science Advisor Research Associate Program, HHS/FDA/ORA, System No. 09–10–0007. First published in the **Federal Register**, September 29, 1977 (42 FR 51922 at 52146); complete text republished in the **Federal Register**, November 24, 1986 (51 FR 42524 at 42530).

2. Radiation Protection Program Personnel Monitoring System, HHS/FDA/CDRH, System No. 09–10–0008. First published in the **Federal Register**, September 29, 1977 (42 FR 51922 at 52147); complete text republished November 24, 1986 (51 FR 42524 at 42531); and published as revised with updated system location and manager information, December 31, 1992 (57 FR 62828 at 62829).

3. Certified Retort Operators, HHS/FDA/CFSAN, System No. 09–10–0011. First published in the **Federal Register**, September 29, 1977 (42 FR 51922 at 52148); complete text republished November 24, 1986 (51 FR 42524 at 42534); and published as revised with minor changes, December 29, 1993 (58 FR 69056).

4. Epidemiological Research Studies of the Center for Devices and Radiological Health, HHS/FDA/CDRH, System No. 09–10–0017. First published in the **Federal Register**, May 29, 1979 (44 FR 30765 at 30766); republished with minor changes in December 28, 1994 (59 FR 67087).

II. Routine Uses To Be Added to the FDA Inventory of SORNS

A. New Routine Uses

For the reasons described in this document, FDA is adding the following routine use disclosures to its SORNs.

1. ''Disclosure may be made to appropriate Federal agencies and Department contractors that have a need to know the information for the purpose of assisting the Department's efforts to respond to a suspected or confirmed breach of the security or confidentiality of information maintained in this system of records, and the information disclosed is relevant and necessary for that assistance.''

The Office of Management and Budget (OMB) and the Department of Health and Human Services (HHS) have directed agencies to include a routine use providing for disclosure of system information to facilitate a Federal level response to a breach of system security. In accordance with OMB Memorandum (M) 07–16, Safeguarding Against and Responding to the Breach of Personally Identifiable Information, HHS policy specifies that all HHS Operating and Staff Divisions incorporate this routine use language as a part of the normal SORN review and publication process. The underlying operational reason for this routine use is that other Federal Agencies, HHS officials and contractors, and FDA contractors may need access to individually identifiable information that is relevant and necessary for assisting in the response to a suspected or confirmed breach of the security or confidentiality of information maintained in systems of records.

Federal law and policy require the Agency to maintain appropriate safeguards for the systems, and, individuals whose data is in the systems expect the Agency to maintain the integrity of their information and secure