structure in order to (1) improve the measurement of covered health topics, (2) reduce respondent burden by shortening the length of the questionnaire and seamlessly integrating supplements, (3) harmonize overlapping content with other federal health surveys, (4) establish a long-term structure of ongoing and periodic topics, and (5) incorporate advances in survey methodology and measurement.

As in past years, and in accordance with the 1995 initiative to increase the integration of surveys within the DHHS, respondents to the 2018 NHIS will serve as the sampling frame for the Medical Expenditure Panel Survey. In addition, a subsample of NHIS respondents and/or members of commercial survey panels may be identified to participate in short, Web-based methodological and cognitive testing activities to evaluate the redesigned questionnaire and/or inform the development of new rotating and supplemental content using Web and/or mail survey tools.

There is no cost to the respondents other than their time. Clearance is sought for three years, to collect data for 2018–2020.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Adult Household Member	Main Household Composition and Family Core.	39,375	1	23/60	15,094
Sample Adult	Main Adult Core	31,500	1	15/60	7,875
Adult Family Member	Main Child Core	12,250	1	10/60	2,042
Adult Family Member	Main Supplements	45,000	1	20/60	15,000
Adult Household Member	Redesigned Family Core	5,625	1	23/60	2,156
Sample Adult	Redesigned Adult Core	4,500	1	15/60	1,125
Adult Family Member	Redesigned Child Core	1,750	1	10/60	292
Adult Family Member	Methodological Projects	15,000	1	20/60	5,000
Adult Family Member	Reinterview Survey	5,000	1	5/60	417
Total					49,000

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2017–17582 Filed 8–18–17; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2013–E–0264; FDA–2013–E–0263; and FDA–2013–E–0218]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

DATES: Anyone with knowledge that any of the dates as published (in the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by October 20, 2017. 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 February 20, 2018. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before October 20, 2017. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of October 20, 2017. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and

identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket Nos. FDA–2013–E–0264; FDA–2013–E–0263; and FDA–2013–E–0218 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; RECUVYRA.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

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

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

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 animal drug products, the testing phase begins on the earlier date when either a major environmental effects test was initiated for the drug or when an exemption under section 512(j) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360b(j)) became effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the animal 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 an animal drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(4)(B).

FDA has approved for marketing the animal drug product RECUVYRA (fentanyl). RECUVYRA is indicated for the control of postoperative pain associated with surgical procedures in dogs. Subsequent to this approval, the USPTO received patent term restoration applications for RECUVYRA (U.S. Patent Nos. 6,299,900; 6,818,226; and 6,916,486) from Acrux DDS Pty. Ltd., and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated April 26, 2016, FDA advised the USPTO that this animal drug product had undergone a regulatory review period and that the approval of RECUVYRA represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for RECUVYRA is 2,092 days. Of this time, 2,037 days occurred during the testing phase of the regulatory review period, while 55 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 FD&C Act (21 U.S.C. 355(i)) became effective:* October 3, 2006. The applicant claims August 31, 2005, as the date the investigational new animal drug application (INAD) became effective. However, FDA records indicate that the INAD effective date was October 3, 2006, which was the date a major health or environmental effects test began.

2. *The date the application was initially submitted with respect to the animal drug product under section 512 of the FD&C Act (21 U.S.C. 360b):* April 30, 2012. The applicant claims April 18, 2012, as the date the new animal drug application (NADA) for RECUVYRA (NADA 141–337) was initially submitted. However, FDA records indicate that NADA 141–337 was submitted on April 30, 2012.

3. *The date the application was approved:* June 23, 2012. FDA has verified the applicant's claim that NADA 141–337 was approved on June 23, 2012.

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 applications for patent extension, this applicant seeks 1,279 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in 21 CFR 60.30, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must be timely (see **DATES**) and 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.

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

Dated: August 15, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–17566 Filed 8–18–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–2363]

Electronic Study Data Submission; Data Standards; Support for Standard for Exchange of Nonclinical Data Implementation Guide Version 3.1

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA or Agency) Center for Drug Evaluation and Research (CDER) is announcing support for the 3.1 version of Clinical Data Interchange Standards Consortium (CDISC) Standard for Exchange of Nonclinical Data (SEND IG 3.1), the end of support for the 3.0 version of SEND IG, and an update to the FDA Data Standards Catalog (Catalog). (See *http://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm*.) SEND IG 3.1 has been available from CDISC (*www.cdisc.org*) since July 2016. FDA is encouraging sponsors and applicants to use SEND IG 3.1 in investigational study data provided in regulatory submissions to CDER.

FOR FURTHER INFORMATION CONTACT: Ron Fitzmartin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1115, Silver Spring, MD 20993–0002, 301–796–5333, email: *CDERDataStandards@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On December 17, 2014, FDA published final guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Standardized Study Data'' (eStudy Data), posted on FDA's Study Data Standards Resources Web page at *https://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm.* The eStudy Data guidance implements the electronic submission requirements of section 745A(a) of the Food, Drug and Cosmetic Act (21 U.S.C. 379k–1(a)) for study data contained in new drug applications (NDAs), abbreviated new drug applications (ANDAs), biologics license applications (BLAs), and investigational new drug applications (INDs) to FDA's Center for Biologics Evaluation and Research or CDER by specifying the format for electronic submissions. The initial timetable for implementing electronic submission requirements for study data was December 17, 2016 (24 months after issuance of final guidance for NDAs, BLAs, ANDAs, and 36 months for INDs). The eStudy Data guidance states that a **Federal Register** notice will specify the transition date for all version updates (with the month and day for the transition date corresponding to March 15).

The transition date for support of version 3.1 of CDISC SEND IG is March 15, 2018. Although SEND IG version 3.1 is supported as of this **Federal Register** notice and sponsors or applicants are encouraged to begin using it, the new version will only be required in submissions for studies that start after March 15, 2019. The Catalog will list March 15, 2019, as the ''date requirement begins.'' When multiple versions of an FDA-supported standard are listed in the Catalog, sponsors or applicants can select a version to use.

The transition date for the end of FDA support for SEND IG 3.0 is March 15, 2018. Therefore, FDA support for SEND IG 3.0 will end for studies that start after March 15, 2019. The Catalog will be updated to list March 15, 2019, as the ''date support ends.''

II. Electronic Access

Persons with access to the Internet may obtain the referenced material at *https://www.fda.gov/ectd.*

Dated: August 15, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–17567 Filed 8–18–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–1956]

Identifying Trading Partners Under the Drug Supply Chain Security Act; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Identifying Trading Partners Under the Drug Supply Chain Security Act'' (draft trading partner guidance). FDA is issuing this guidance to assist industry and State and local governments in understanding how to categorize the entities in the drug supply chain in accordance with the Drug Supply Chain Security Act (DSCSA). This guidance explains how to determine when certain statutory requirements will apply to entities that may be considered trading partners in the drug supply chain. FDA is also soliciting public input specific to the activities of ''private-label distributors'' of drug products and whether those activities fall within the definitions under DSCSA of the various trading partners.

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 comment 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 October 20, 2017.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').