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 998 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 § 60.30 (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 comply with all the requirements of § 60.30, including but not limited to: Must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (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: September 17, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–20657 Filed 9–23–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–4212]

Wholesale Distributor Verification Requirement for Saleable Returned Drug Product—Compliance Policy; 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 final guidance for industry entitled ''Wholesale Distributor Verification Requirement for Saleable Returned Drug Product—Compliance Policy.'' This guidance describes FDA's intention regarding enforcement of the Drug Supply Chain Security Act (DSCSA) provision requiring wholesale distributors to verify a product identifier prior to further distributing returned product beginning on November 27, 2019. Given concerns expressed by stakeholders and to minimize possible disruptions in the pharmaceutical distribution supply chain, FDA does not intend to take action against wholesale distributors who do not, prior to November 27, 2020, verify a product identifier prior to further distributing returned product as required under the DSCSA. This represents a 1-year delay in enforcement of this DSCSA requirement.

DATES: The announcement of the guidance is published in the **Federal Register** on September 24, 2019.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time 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'').

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 No. FDA–2019–D–4212 for ''Wholesale Distributor Verification Requirement for Saleable Returned Drug Product—Compliance Policy.'' Received comments 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002, or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Sarah Venti, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–3130, *drugtrackandtrace@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Wholesale Distributor Verification Requirement for Saleable Returned Drug Product—Compliance Policy.'' FDA is issuing this guidance consistent with the good guidance practices regulation (21 CFR 10.115). FDA is implementing this guidance without prior public comment because the Agency has determined that prior public participation is not feasible or appropriate (21 CFR 10.115(g)(2)). FDA made this determination because this guidance document provides information pertaining to the statutory requirement that takes effect November 27, 2019, for wholesale distributors to verify saleable returned drug products prior to redistribution under section 582(c)(4)(D) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360eee–1(c)(4)(D)). It is important that FDA provide this information before that date. Although this guidance document is immediately in effect, it remains subject to comment in accordance with the Agency's good guidance practices (21 CFR 10.115(g)(3)).

The DSCSA (Title II of Pub. L. 113–54) was signed into law on November 27, 2013. Section 202 of the DSCSA added section 582 to the FD&C Act. This section established product tracing, product identifier, authorized trading partner, and verification requirements for manufacturers, wholesale distributors, repackagers, and dispensers to facilitate the tracing of a product through the pharmaceutical distribution supply chain. Failure to comply with the requirements of section 582 is prohibited under section 301(t) of the FD&C Act (21 U.S.C. 331(t)) and subject to enforcement action under the FD&C Act.

Beginning November 27, 2019, wholesale distributors are required, under section 582(c)(4)(D) of the FD&C Act, to verify the product identifier, including the standardized numerical identifier, on each sealed homogeneous case of saleable returned product, or, if such product is not in a sealed homogeneous case, on each package of saleable returned product, prior to further distributing such returned product.

As described in the guidance, FDA has received comments and feedback from wholesale distributors as well as other trading partners and stakeholders expressing concern with industry-wide readiness for implementation of the verification of saleable returned product requirement for wholesale distributors and the challenges stakeholders face with developing interoperable, electronic systems to enable such verification and achieve interoperability between networks. Given the concerns expressed, FDA recognizes that some wholesale distributors may need additional time beyond November 27, 2019, before they can begin verifying the product identifier on returned products prior to further distribution in an efficient, secure, and timely manner.

To minimize possible disruptions in the distribution of prescription drugs in the United States, FDA has adopted the compliance policy described in this guidance. Under this compliance policy, FDA does not intend to take action before November 27, 2020, against wholesale distributors who do not verify a product identifier prior to further distribution of a package or sealed homogenous case of product as required by section 582(c)(4)(D) of the FD&C Act.

Additionally, section 582 of the FD&C Act requires certain trading partners (manufacturers, repackagers, wholesale distributors, and dispensers) to exchange transaction information, transaction history, and a transaction statement when engaging in transactions involving certain prescription drugs. Section 581(27)(E) of the FD&C Act (21 U.S.C. 360eee(27)(E)) requires that the transaction statement include a statement that the entity transferring ownership in a transaction had systems and processes in place to comply with verification requirements under section 582. This guidance also explains that, prior to November 27, 2020, FDA does not intend to take action against a wholesale distributor for providing a transaction statement to a subsequent purchaser of product on the basis that such wholesale distributor does not yet have systems and processes in place to comply with the saleable return verification requirements under section 582(c)(4)(D). The guidance document explains the scope of the compliance policy in further detail.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance represents the current thinking of FDA on ''Wholesale Distributor Verification Requirement for Saleable Returned Drug Product—Compliance Policy.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics,* or *https://www.regulations.gov.*

Dated: September 18, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–20651 Filed 9–23–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0035]

Amyotrophic Lateral Sclerosis: Developing Drugs for Treatment; 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 final guidance for industry entitled ''Amyotrophic Lateral Sclerosis: Developing Drugs for Treatment.'' The guidance provides FDA's current thinking on the clinical development program and clinical trial designs for drugs to support an indication for the treatment of amyotrophic lateral