SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier.'' On November 27, 2013, the Drug Supply Chain Security Act (DSCSA) (Title II of Pub. L. 113–54) was signed into law. Section 202 of the DSCSA added section 582 to the FD&C Act (21 U.S.C. 360eee–1), which established product tracing requirements for manufacturers, repackagers, wholesale distributors, and dispensers. The DSCSA phases in its requirements over a 10-year period.

A critical set of phased product tracing requirements outlined in section 582 of the FD&C Act relates to the product identifier. Among its provisions, section 582 of the FD&C Act requires that each package and homogenous case of product in the pharmaceutical distribution supply chain bear a product identifier that is encoded with the product's standardized numerical identifier, lot number, and expiration date by specific dates. Under the statute, manufacturers were required to begin affixing or imprinting a product identifier to each package and homogenous case of a product intended to be introduced into commerce no later than November 27, 2017. Repackagers are required to do the same no later than November 27, 2018.

Sections 582(c)(2), (d)(2), and (e)(2)(A)(iii) of the FD&C Act restrict trading partners' ability to engage in transactions involving packages and homogenous cases of product that are not labeled with a product identifier after specific dates. Beginning November 27, 2018, repackagers may not engage in a transaction involving a package or homogenous case of a product that is not encoded with a product identifier. Similar restrictions go into effect for wholesale distributors and dispensers on November 27, 2019, and November 27, 2020, respectively.

In addition, section 582 of the FD&C Act requires trading partners to verify product identifiers on packages and homogenous cases starting on November 27, 2017, for manufacturers (section 582(b)(4)); on November 27, 2019, for wholesale distributors (section 582(c)(4)); on November 27, 2020, for dispensers (section 582(d)(4)); and on November 27, 2018, for repackagers (section 582(e)(4)). Manufacturers, repackagers, wholesale distributors, and dispensers are also required to verify the product identifier of a saleable returned package or sealed homogenous case on November 27, 2017, November 27, 2018, November 27, 2019, and November 27, 2020, respectively.

In section 582(a)(5)(A) of the FD&C Act, Congress directed FDA to issue guidance specifying ''whether and under what circumstances product that is not labeled with a product identifier and that is in the pharmaceutical supply chain at the time at the time of the effective date of the requirements of [section 582] shall be exempted'' from the product tracing requirements discussed previously. The guidance addresses this requirement. As explained in the guidance, only packages and homogenous cases of product that are in the pharmaceutical distribution supply chain at the time of the effective date of the requirements of section 582 are eligible for grandfathering under section 582(a)(5)(A) of the FD&C Act.

In the **Federal Register** of November 27, 2017 (82 FR 56033), FDA issued a notice announcing the availability of the draft version of this guidance. The comment period for the draft guidance ended January 26, 2018. FDA received approximately 10 comments on the draft guidance. In response to received comments or on its own initiative, FDA made several changes. The most significant change FDA made was to revise the grandfathering exemption to include products repackaged by a repackager before November 27, 2018. FDA made this change in response to comments indicating that repackagers will need time beyond November 27, 2018, to sell such product. In addition, FDA made editorial and formatting changes to improve clarity.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier.'' It does not establish any rights for any person and, with the exception of specified material in section IV, 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 *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm,* or *https://www.regulations.gov.*

Dated: September 14, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–20503 Filed 9–19–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–2167]

Heparin-Containing Medical Devices and Combination Products: Recommendations for Labeling and Safety Testing; Guidance for Industry and Food and Drug Administration Staff; 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 entitled ''Heparin-Containing Medical Devices and Combination Products: Recommendations for Labeling and Safety Testing.'' The United States Pharmacopeia (USP) drug substance monograph for Heparin Sodium, and drug product monographs for Heparin Lock Flush Solution and Heparin Sodium Injection, recently have undergone several revisions following serious and fatal events related to the use of heparin sodium products. Investigation of heparin product overdose errors identified the expression of drug strength in the labels as a major contributing factor in these errors. This guidance document addresses these safety concerns by clarifying new expectations for labeling with regard to the revised heparin USP monographs, as well as outlining safety testing recommendations.

DATES: The announcement of the guidance is published in the **Federal Register** on September 20, 2018.

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–2015–D–2167 for ''Heparin-Containing Medical Devices and Combination Products: Recommendations for Labeling and Safety Testing.'' 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)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Heparin-Containing Medical Devices and Combination Products: Recommendations for Labeling and Safety Testing'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Andrew Yeatts, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1643, Silver Spring, MD 20993–0002, 301–796–4539.

SUPPLEMENTARY INFORMATION:

I. Background

The USP [1] heparin monographs have recently undergone several revisions following serious and fatal events related to the use of heparin sodium products. Investigation of heparin product overdose errors identified the expression of drug strength in the labels as a major contributing factor in these errors. This guidance document addresses these safety concerns by clarifying new expectations for labeling with regard to the revised heparin USP monographs, as well as outlining safety testing recommendations.

In addition, the outbreak of serious and often fatal events due to heparin contamination with over-sulfated chondroitin sulfate in 2008 led the USP to include in its monograph additional testing of heparin source material to ensure its quality and purity. This guidance also outlines use of conformance to the monograph in premarket submissions, specifically testing and documentation requirements and/or recommendations contained in the current USP monographs and the guidance document ''Heparin for Drug and Medical Device Use: Monitoring Crude Heparin for Quality'' (*https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM291390.pdf*).[2]

FDA considered comments received on the draft guidance that appeared in the **Federal Register** of July 9, 2015 (80 FR 39440). FDA revised the guidance as appropriate in response to the comments.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Heparin-Containing Medical Devices and Combination Products: Recommendations for Labeling and Safety Testing.'' 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.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* This

[1] USP is a scientific nonprofit organization that develops standards for the identity, strength, quality, and purity of drugs and drug ingredients marketed in the United States. These standards are published in USP's official compendia, U.S. Pharmacopeia and National Formulary.

[2] The Agency updates guidances periodically. To make sure you have the most recent version of this guidance, check the FDA guidance page at *https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.*

guidance is also available at *https://www.regulations.gov.* Persons unable to download an electronic copy of ''Heparin-Containing Medical Devices and Combination Products: Recommendations for Labeling and Safety Testing'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1817 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in the following FDA regulations and guidance have been approved by OMB as listed in the following table:

21 CFR part; guidance; or FDA form	Topic	OMB control No.
211	Current good manufacturing practice for finished pharmaceuticals	0910–0139
807, subpart E	Premarket notification	0910–0120
814, subparts A through E	Premarket approval	0910–0231
814, subpart H	Humanitarian Device Exemption	0910–0332
812	Investigational Device Exemption	0910–0078
''De Novo Classification Process (Evaluation of Automatic Class III Designation)''.	De Novo classification process	0910–0844
801	Medical Device Labeling Regulations	0910–0485
803	Medical Devices; Medical Device Reporting; Manufacturer reporting, importer reporting, user facility reporting, distributor reporting.	0910–0437
820	Quality System (QS) Regulation	0910–0073

Dated: September 17, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–20472 Filed 9–19–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–2232]

Product Identifier Requirements Under the Drug Supply Chain Security Act—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 ''Product Identifier Requirements Under the Drug Supply Chain Security Act—Compliance Policy.'' This guidance describes FDA's intention with regard to enforcement of the Drug Supply Chain Security Act (DSCSA) provision requiring manufacturers to begin affixing or imprinting product identifiers on their products beginning November 27, 2017. This guidance finalizes the draft guidance issued on July 3, 2017.

DATES: The announcement of the guidance is published in the **Federal Register** on September 20, 2018.

ADDRESSES: You may submit either electronic or written comments on Agency Guidance 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–2017–D–2232 for ''Product Identifier Requirements Under the Drug Supply Chain Security Act—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