Application No.	Drug	Applicant
ANDA 065484 ..	Cefuroxime Sodium for Injection, EQ 7.5 g base/vial Pharmacy Bulk Package.	Do.
ANDA 065503 ..	Cefuroxime Sodium for Injection, EQ 1.5 g base/vial	Do.
ANDA 075250 ..	Prednisolone Sodium Phosphate Oral Solution, EQ 15 mg base/5 milliliters (mL).	Bausch Health US, LLC, 400 Somerset Corporate Blvd., Bridgewater, NJ 08807.
ANDA 075618 ..	Acetaminophen, Butalbital, Caffeine, and Codeine Phosphate Capsules, 325 mg, 50 mg, 40 mg, and 30 mg.	Hikma Pharmaceuticals USA Inc., 1809 Wilson Rd., Columbus, OH 43228.
ANDA 090375 ..	Ampicillin and Sulbactam for Injection, EQ 1 g base/vial and EQ 500 mg base/vial; EQ 2 g base/vial and EQ 1 g base/vial.	Hospira, Inc.
ANDA 090646 ..	Ampicillin and Sulbactam for Injection, EQ 10 g base/vial and EQ 5 g base/vial.	Do.
ANDA 090653 ..	Ampicillin and Sulbactam for Injection, EQ 1 g base/vial and EQ 500 mg base/vial; EQ 2 g base/vial and EQ 1 g base/vial.	Do.
ANDA 090825 ..	Imipenem and Cilastatin for Injection, EQ 250 mg base/vial and 250 mg base/vial; EQ 500 mg base/vial and 500 mg/vial.	Do.
ANDA 090940 ..	Meropenem for Injection, 500 mg/vial, and 1 g/vial	Do.
ANDA 091007 ..	Imipenem and Cilastatin for Injection, EQ 500 mg base/vial and 500 mg/vial.	Do.
ANDA 202268 ..	Cefepime HCl for Injection, EQ 1 g base/vial; EQ 2 g base/vial.	Do.
ANDA 202563 ..	Ceftriaxone for Injection, EQ 1 g base/vial; EQ 2 g base/vial ..	Do.
ANDA 202864 ..	Ampicillin Sodium for Injection, EQ 250 mg base/vial; EQ 500 mg base/vial; EQ 1 g base/vial; EQ 2 g base/vial.	Do.
ANDA 202865 ..	Ampicillin Sodium for Injection, EQ 10 g base/vial Pharmacy Bulk Package.	Do.
ANDA 203132 ..	Cefotaxime Sodium for Injection, EQ 1 g base/vial; EQ 2 g base/vial.	Do.
ANDA 204879 ..	Pyridoxine HCl Injection, 100 mg/mL	Mylan Institutional, LLC, 4901 Hiawatha Dr., Rockford, IL 61103.
ANDA 206062 ..	Doxorubicin HCl for Injection, USP, 20 mg/vial	Hisun Pharmaceutical Hangzhou Co., LTD, 200 Crossing Blvd., 2nd Floor, Bridgewater, NJ 08807.
ANDA 206195 ..	Daunorubicin HCl for Injection, EQ 20 mg base/vial	Do.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of March 16, 2020. Approval of each entire application is withdrawn, including any strengths or products inadvertently missing from the table. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on March 16, 2020 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: February 11, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–03025 Filed 2–13–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–1398]

Mitigation Strategies To Protect Food Against Intentional Adulteration; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, we, or Agency) is announcing the availability of a supplemental draft guidance for industry entitled ''Mitigation Strategies to Protect Food Against Intentional Adulteration: Guidance for Industry.'' This supplemental draft guidance document, when finalized, will help food facilities that manufacture, process, pack, or hold food, and that are required to register under the Federal Food, Drug, and Cosmetic Act (FD&C Act) comply with the requirements of our regulation entitled ''Mitigation Strategies to Protect Food Against Intentional Adulteration.''

DATES: Submit either electronic or written comments on the draft guidance by June 15, 2020 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any 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–2018–D–1398 for ''Mitigation Strategies to Protect Food Against Intentional Adulteration: Guidance for Industry.'' 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.govinfo.gov/content/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 the guidance to the Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Ryan Newkirk, Center for Food Safety and Applied Nutrition (HFS–005), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–3712, *ryan.newkirk@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353) enables FDA to better protect public health by helping to ensure the safety and security of the food supply. FSMA enables FDA to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur.

FSMA added to the FD&C Act several new sections that reference intentional adulteration. For example, section 418 of the FD&C Act (21 U.S.C. 350g) addresses intentional adulteration in the context of facilities that manufacture, process, pack, or hold food, and that are required to register under section 415 (21 U.S.C. 350d). Section 420 of the FD&C Act (21 U.S.C. 350i) addresses intentional adulteration in the context of high-risk foods and exempts farms except for farms that produce milk.

We are announcing the availability of a supplemental draft guidance for industry entitled ''Mitigation Strategies to Protect Food Against Intentional Adulteration: Guidance for Industry.'' This multi-chapter supplemental draft guidance for industry is intended to help food facilities required to comply develop and implement some of the components of a food defense plan, and meet other requirements under 21 CFR part 121. We are announcing the availability of the following chapters and appendices:

- Chapter 5—Mitigation Strategies Management Components: Food Defense Corrective Actions
- Chapter 6—Mitigation Strategies Management Components: Food Defense Verification
- Chapter 7—Reanalysis
- Chapter 9—Records
- Appendix 2—Mitigation Strategies in the Food Defense Mitigation Strategies Database
- Appendix 3—Determination of Status as a Very Small Business or Small Business Under Part 121: Mitigation Strategies to Protect Food Against Intentional Adulteration

II. Significance of Guidance

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on food defense measures against intentional adulteration for the regulation ''Mitigation Strategies to Protect Food Against Intentional Adulteration.'' 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.

III. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. 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 21 CFR part 121 have been approved under OMB control number 0910–0812.

IV. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/regulatory-information/search-fda-guidance-documents* or *https://www.regulations.gov.* Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: February 10, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–02986 Filed 2–13–20; 8:45 am]

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