The reorganization retitled OCE as the Office of Communication, Information Disclosure, Training, and Education (OCITE); abolished the Digital Communication Media Staff; established the Office of Communication and Content Development (OCCD) and the Office of Training and Education (OTE) within OCITE, established the Division of Digital Communication and Marketing (DDCM) within OCCD, and realigned the existing divisions to the new offices.

DCCE. ORGANIZATION. CDRH's OCITE is headed by the Director, and includes the following:

Office of Communication, Information Disclosure, Training, and Education (DCCE)

Program Management Operations Staff (DCCE1)

Office of Communication and Content Development (DCCEE)

Division of Communication (DCCEEA)

Division of Information Disclosure (DCCEEB)

Division of Digital Communication and Marketing (DCCEEC)

Office of Training and Education (DCCEF)

Division of Employee Training and Development (DCCEFA)

Division of Industry and Consumer Education (DCCEFB)

II. Delegations of Authority

Pending further delegation, directives, or orders by the Commissioner of Food and Drugs, all delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegations, provided they are consistent with this reorganization.

III. Electronic Access

This reorganization is reflected in FDA's Staff Manual Guide (SMG). Persons interested in seeing the complete SMG can find it on FDA's website at: *https://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/default.htm.*

(Authority: 44 U.S.C. 3101).

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2024–09381 Filed 5–6–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Statement of Organization, Functions, and Delegations of Authority

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA), Center for Devices and Radiological Health's (CDRH), Office of Product Evaluation and Quality (OPEQ) has modified their organizational structure. The new organizational structure was approved by the Secretary of Health and Human Services on December 21, 2023, and it became effective on January 22, 2024.

FOR FURTHER INFORMATION CONTACT: Yashika Rahaman, Director, Office of Planning, Evaluation and Risk Management, Office of Finance, Budget, Acquisitions and Planning, Food and Drug Administration, 4041 Powder Mill Rd., Beltsville, MD 20705–4304, 301–796–3843.

I. Introduction

Part D, Chapter D–B, (Food and Drug Administration), the Statement of Organization, Functions and Delegations of Authority for the Department of Health and Human Services (35 FR 3685, February 25, 1970, 60 FR 56606, November 9, 1995, 64 FR 36361, July 6, 1999, 72 FR 50112, August 30, 2007, 74 FR 41713, August 18, 2009, 76 FR 45270, July 28, 2011, and 84 FR 22854, May 20, 2019) is amended to reflect the reorganization of the CDRH OCE.

The reorganization of OPEQ impacted the OPEQ's Office of Clinical Evidence and Analysis (OCEA) and the OPEQ's Office of Health Technology IV (OHT IV). OCEA established the Division of Clinical Evidence and Analysis IV and the Division of Clinical Evidence and Analysis V. OHT IV established the Division of Health Technology IV C.

DCCFB. ORGANIZATION. CDRH's OPEQ OCEA is headed by the Director, and includes the following:

Office of Clinical Evidence and Analysis (DCCFB)

Division of Clinical Evidence and Analysis I (DCCFBA)

Division of Clinical Evidence and Analysis II (DCCFBB)

Division of Clinical Evidence and Analysis III (DCCFBC)

Division of Clinical Evidence and Analysis IV (DCCFBD)

Division of Clinical Evidence and Analysis V (DCCFBE)

DCCFF. ORGANIZATION. CDRH's OPEQ OHT IV is headed by the Director, and includes the following:

Office of Health Technology IV (DCCFF)

Division of Health Technology IV A (DCCFFA)

Division of Health Technology IV B (DCCFFB)

Division of Health Technology IV C (DCCFFC)

II. Delegations of Authority

Pending further delegation, directives, or orders by the Commissioner of Food and Drugs, all delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegations, provided they are consistent with this reorganization.

III. Electronic Access

This reorganization is reflected in FDA's Staff Manual Guide (SMG). Persons interested in seeing the complete SMG can find it on FDA's website at: *https://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/default.htm.*

(Authority: 44 U.S.C. 3101).

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2024–09382 Filed 5–6–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–1917]

Fresenius Kabi USA, LLC, et. al.; Withdrawal of Approval of 12 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 12 abbreviated new drug applications (ANDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of June 6, 2024.

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New

Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993–0002, 240–402–6980, *Martha.Nguyen@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process described in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
ANDA 040379	Fluorouracil Injectable, 50 milligrams (mg)/milliliter (mL)	Fresenius Kabi USA, LLC, Three Corporate Dr., Lake Zurich, IL 60047.
ANDA 062901	Ampicillin Sodium; Sulbactam Sodium Injectable, Equivalent to (EQ) 2 grams (gm) base/vial; EQ 1 gm base/vial, and EQ 1 gm base/vial; EQ 500 mg base/vial.	Pfizer Inc., 66 Hudson Blvd East, New York, NY 10001.
ANDA 071981	Droperidol Injectable, 2.5 mg/mL	Hospira Inc., 275 North Field Dr., Bldg. H1–3S, Lake Forest, IL 60045.
ANDA 202546	Ribavirin Tablets, 200 mg, 400 mg, 500 mg, and 600 mg	RegCon Solutions, LLC, U.S. Agent for Beximco Pharmaceuticals USA Inc., 10525 Vista Sorrento Parkway, Suite 100, San Diego, CA 92121.
ANDA 203544	Sodium Fluoride F–18 Injectable, 10–200 millicurie (mCi)/mL	SOFIE Co. dba SOFIE, 21000 Atlantic Blvd., Suite 730, Dulles, VA 20166.
ANDA 203773	Dexmedetomidine Hydrochloride (HCl) Injectable, EQ 200 microgram (mcg) base/2 mL (EQ 100 mcg base/mL).	American Regent, Inc., 5 Ramsey Rd., Shirley, NY 11967.
ANDA 203884	Amiodarone HCl Injectable, 50 mg/mL	Hospira Inc.
ANDA 204315	Sodium Fluoride F–18 Injectable, 10–200 mCi/mL	B&H Consulting Services, Inc., U.S. Agent for Shertech Laboratories, LLC, 50 Division St., Suite 206, Somerville, NJ 08876.
ANDA 204366	Ammonia N 13 Injectable, 3.75–260 mCi/mL	Do.
ANDA 204854	Meropenem for Injection, 500 mg/vial and 1 gm/vial	Freyr Inc., U.S. Agent for Daewoong Pharmaceutical Co., Ltd., 150 College Rd. West, Suite 102, Princeton, NJ 08540.
ANDA 206710	Paricalcitol Capsules, 1 mcg, 2 mcg, and 4 mcg	Alvogen PB Research and Development LLC, U.S. Agent for Lotus Pharmaceutical Co., Ltd. Nantou Plant, 44 Whippany Rd., Suite 300, Morristown, NJ 07960.
ANDA 208695	Bosentan Tablets, 62.5 mg, and 125 mg	Hikma Pharmaceuticals USA Inc., 1809 Wilson Rd., Columbus, OH 43228.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of June 6, 2024. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from the table. Introduction or delivery for introduction into interstate commerce of products listed in the table without an approved new drug application or ANDA violates sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d)). Drug products that are listed in the table that are in inventory on June 6, 2024 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: May 2, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–09914 Filed 5–6–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–3827]

Adam Paul Runsdorf: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) permanently debarring Adam Paul Runsdorf from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Mr. Runsdorf was convicted of a felony under Federal law for conduct that relates to the regulation of a drug product under the FD&C Act. Mr. Runsdorf was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. As of February 25, 2024 (30 days after receipt of the notice), Mr. Runsdorf has not responded. Mr. Runsdorf's failure to respond and request a hearing constitutes a waiver of Mr. Runsdorf's right to a hearing concerning this matter.

DATES: This order is applicable May 7, 2024.

ADDRESSES: Any application by Mr. Runsdorf for special termination of debarment under section 306(d)(4) of the FD&C Act (21 U.S.C. 335a(d)(4)) may be submitted at any time as follows:

Electronic Submissions

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. An application submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your application will be made public, you are solely responsible for ensuring that your application 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