ingredient to the approved inert list is a prerequisite to approval of applications for registration of specific pesticide formulations that contain the inert ingredient. Approval of a registration application does incorporate risk and considers risks resulting from the formulation of the pesticide product including its inert ingredients.

As of the date of this notice, EPA is removing the twelve chemicals listed here from the current list of inert ingredients approved for use in pesticide products. These twelve chemicals are for nonfood use only and there are no food residue considerations related to this action.

Authority: 7 U.S.C. 136 *et seq.*

Dated: December 8, 2022.

Michal Freedhoff,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2022–27085 Filed 12–13–22; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm.* Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)).

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than January 13, 2023.

A. Federal Reserve Bank of Atlanta (Erien O. Terry, Assistant Vice President) 1000 Peachtree Street NE, Atlanta, Georgia 30309; Comments can also be sent electronically to *Applications.Comments@atl.frb.org:*

1. *Surety Financial Holdings, Inc., DeLand, Florida;* to become a bank holding company by acquiring Surety Bank, DeLand, Florida.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2022–27139 Filed 12–13–22; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1262]

Notice of Approval of Product Under Voucher: Rare Pediatric Disease Priority Review Voucher

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of approval of a product redeeming a priority review voucher. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA is required to publish notice of the issuance of priority review vouchers as well as the approval of products redeeming a priority review voucher. FDA has determined that TYVASO DPI (treprostinil), approved May 23, 2022, meets the criteria for redeeming a priority review voucher.

FOR FURTHER INFORMATION CONTACT: Cathryn Lee, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–1394, email: *Cathryn.Lee@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA is announcing the approval of a product redeeming a rare pediatric disease priority review voucher. Under section 529 of the FD&C Act (21 U.S.C. 360ff), which was added by FDASIA, FDA will report the issuance of rare pediatric disease priority review vouchers and the approval of products for which a voucher was redeemed. FDA has determined that the supplemental application for TYVASO DPI (treprostinil), approved May 23, 2022, meets the redemption criteria.

For further information about the Rare Pediatric Disease Priority Review Voucher Program and for a link to the full text of section 529 of the FD&C Act, go to *https://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/RarePediatricDiseasePriorityVoucherProgram/default.htm.* For further information about TYVASO DPI (treprostinil), approved May 23, 2022, go to the ''Drugs@FDA'' website at *https://www.accessdata.fda.gov/scripts/cder/daf/.*

Dated: December 9, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–27138 Filed 12–13–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0521]

David J. Kempema: 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) debarring David J. Kempema for a period of 5 years from importing or offering for import any drug into the United States. FDA bases this order on a finding that Mr. Kempema was convicted of one felony count under Federal law which FDA has determined is for conduct relating to the importation into the United States of a drug or controlled substance. The factual basis supporting Mr. Kempema's conviction is described in further detail below. Mr. Kempema was given notice of the proposed debarment and was given an opportunity to request a hearing to show why he should not be debarred. As of September 14, 2022 (30 days after receipt of the notice), Mr. Kempema had not responded. Mr. Kempema's failure to respond and request a hearing constitutes a waiver of his right to a hearing concerning this matter.

DATES: This order is applicable December 14, 2022.

ADDRESSES: Submit applications for termination of debarment to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500, or at *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, Division of Enforcement (ELEM–4144), Office of Strategic Planning and Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 240–402–8743, or at *debarments@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(1)(D) of the FD&C Act (21 U.S.C. 335a(b)(1)(D)) permits debarment of an individual from importing or offering for import any drug into the United States if FDA finds, as required by section 306(b)(3)(C) of the FD&C Act, that the individual has been convicted of a felony for conduct relating to the importation into the United States of any drug or controlled substance.

On March 15, 2022, Mr. Kempema was convicted, as defined in section 306(l)(1) of FD&C Act, in the U.S. District Court for Northern District of Iowa, when the court entered judgment against him for the offense of Introduction into Interstate Commerce of Misbranded Drugs with Intent to Defraud After Having Been Previously Convicted of an Offense under 21 U.S.C. 331 and 333 in violation of sections 301(a), 301(k), and 303(a)(2) of the FD&C Act (21 U.S.C. 331(a), 331(k), and 333(a)(2)). FDA's finding that debarment is appropriate is based on the felony conviction referenced herein. The factual basis for this conviction is as follows: As contained in the Information, filed on October 4, 2021, and in the Plea Agreement from Mr. Kempema's case, Mr. Kempema was previously convicted, on February 8, 2012, of one count of introducing and causing the introduction of misbranded drugs into interstate commerce, and causing the misbranding of drugs held for sale after shipment in interstate commerce with intent to defraud or mislead, in violation of sections 301(a), 301(k), and 303(a)(2) of the FD&C Act in *U.S.* v. *David Kempema,* No. 5:11–cr–04140–MWB (N.D. Iowa). In that case, between October 2009 and July 2011, Mr. Kempema ordered pills from India that contained the same active ingredients as Viagra and Cialis, but that had not been approved by FDA for sale in the United States. Mr. Kempema then sold the non-FDA approved pills to U.S. consumers as Viagra and Cialis.

Subsequently, from about February 2014 through about December 2018, Mr. Kempema was the owner and operator of Canned Ads, a business located in Iowa. During that time, he obtained Silditop, Aurogra, and Tadalista pills from India and/or Germany. Mr. Kempema found suppliers by searching the internet for generic Viagra and Cialis. He then purchased the drugs online from vendors overseas and received the products at the location of his business Canned Ads in Iowa. Both Silditop and Aurogra were new drugs that contained sildenafil, the active ingredient in Viagra, while Tadalista was a new drug that contained tadalafil, the active ingredient in Cialis. Silditop, Aurogra, and Tadalista had not been approved by FDA for sale or distribution in the United States. FDA approved drugs containing the active ingredients sildenafil and tadalafil are only available by prescription, and the labeling for those products includes numerous warnings, including a warning that those drugs can cause blood pressure to drop suddenly to an unsafe level if taken with certain other medications.

Mr. Kempema placed advertisements that made claims about male enhancement dietary supplements in men's restrooms in businesses in Iowa, in truck stops along the Interstate 29 corridor, and other locations. If a customer placed an order with Mr. Kempema for male enhancement dietary supplements, he would supply the customer with Silditop, Aurogra, and/or Tadalista. Mr. Kempema did not identify the drugs he sold as Silditop, Aurogra, and/or Tadalista. Instead, Mr. Kempema offered the drugs for sale under the names of other drugs, such as ''All Natural Male.'' Mr. Kempema shipped the drugs to customers both inside and outside of the State of Iowa. The labeling on the drugs he shipped customers did not contain adequate directions for use and Mr. Kempema dispensed these prescription drugs without the prescription of a practitioner licensed by law to administer the drugs. During the course of this offense, Mr. Kempema obtained and attempted to obtain at least 4,059 pills for resale.

An undercover FDA agent made 3 controlled purchases from Mr. Kempema over a period of time for a product Mr. Kempema characterized as a dietary supplement called ''All Natural Male'' which came in the form of tablets in a pack of 10 at a cost of $5 per tablet. During the first controlled purchase, the agent purchased $50 worth of tablets from Mr. Kempema, which he shipped to the agent. FDA testing later revealed that the tablets the undercover FDA agent purchased contained sildenafil, an undeclared erectile dysfunction drug. After the FDA undercover agent made the second controlled purchase, Mr. Kempema shipped the agent two 10-count blister packs of Silditop 100 Sildenafil Citrate tablets IP 100mg. The labeling for the products indicated they had been manufactured in India by Centurion Remedies PVT.LTD, for Healing Pharma, and FDA confirmed the products were not approved for sale or distribution in the United States. After the third controlled purchase, Mr. Kempema shipped the undercover FDA agent two 10-count blister packets with labeling that indicated the products were ''Aurogra 100'' Sildenafil Tablets 100mg. The labeling listed the manufacturer as ''Aurochem Pharmaceuticals'' of India, and FDA confirmed the products were not approved for sale or distribution in United States.

As a result of this conviction, FDA sent Mr. Kempema, by certified mail, on August 9, 2022, a notice proposing to debar him for a 5-year period from importing or offering for import any drug into the United States. The proposal was based on a finding under section 306(b)(3)(C) of the FD&C Act that Mr. Kempema's felony conviction under Federal law for Introduction into Interstate Commerce of Misbranded Drugs with Intent to Defraud After Having Been Previously Convicted of an Offense under sections 301(a), 301(k), and 303(a)(2) of the FD&C Act was for conduct relating to the importation into the United States of any drug or controlled substance because he illegally imported and introduced misbranded prescription drug products into interstate commerce. In proposing a debarment period, FDA weighed the considerations set forth in section 306(c)(3) of the FD&C Act that it considered applicable to Mr. Kempema's offense and concluded that the offense warranted the imposition of a 5-year period of debarment.

The proposal informed Mr. Kempema of the proposed debarment and offered him an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Mr. Kempema received the proposal and notice of opportunity for a hearing on August 15, 2022. Mr. Kempema failed to request a hearing within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a

hearing and waived any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(b)(3)(C) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Mr. David J. Kempema has been convicted of a felony under Federal law for conduct relating to the importation into the United States of any drug or controlled substance. FDA finds that the offense should be accorded a debarment period of 5 years as provided by section 306(c)(2)(A)(iii) of the FD&C Act.

As a result of the foregoing finding, Mr. Kempema is debarred for a period of 5 years from importing or offering for import any drug into the United States, effective (see **DATES**). Pursuant to section 301(cc) of the FD&C Act (21 U.S.C. 331(cc)), the importing or offering for import into the United States of any drug by, with the assistance of, or at the direction of Mr. Kempema is a prohibited act.

Any application by Mr. Kempema for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA–2022–N–0521 and sent to the Dockets Management Staff (see **ADDRESSES**). The public availability of information in these submissions is governed by 21 CFR 10.20(j).

Publicly available submissions will be placed in the docket and will be viewable at *https://www.regulations.gov* or at the Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

Dated: December 8, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–27091 Filed 12–13–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–1050]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Targeted Mechanism of Action Presentations in Prescription Drug Promotion

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing that a collection of information entitled ''Targeted Mechanism of Action Presentations in Prescription Drug Promotion'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA).

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, *301–796–3794, PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On October 14, 2022, the Agency submitted a proposed collection of information entitled ''Targeted Mechanism of Action Presentations in Prescription Drug Promotion'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0908. The approval expires on November 30, 2025. A copy of the supporting statement for this information collection is available on the internet at *https://www.reginfo.gov/public/do/PRAMain.*

Dated: December 9, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–27140 Filed 12–13–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–2969]

Advisory Committee; Endocrinologic and Metabolic Drugs Advisory Committee; Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of Federal advisory committee.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of the Endocrinologic and Metabolic Drugs Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Endocrinologic and Metabolic Drugs Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until the August 27, 2024, expiration date.

DATES: Authority for the Endocrinologic and Metabolic Drugs Advisory Committee will expire on August 27, 2024, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: LaToya Bonner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–2855, *EMDAC@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102–3.65 and approval by the Department of Health and Human Services and by the General Services Administration, FDA is announcing the renewal of the Endocrinologic and Metabolic Drugs Advisory Committee (the Committee). The Committee is a discretionary Federal advisory committee established to provide advice to the Commissioner. The Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which FDA has regulatory responsibility.

The Committee reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of endocrine and metabolic disorders and makes appropriate recommendations to the Commissioner.

The Committee shall consist of a core of 11 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of endocrinology, metabolism, epidemiology or statistics, and related specialties. Members will be invited to serve for overlapping terms of up to 4 years. Non-Federal members of this committee will serve as Special Government Employees, representatives, or Ex-Officio members. Federal members will serve as Regular Government Employees or Ex-Officios. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one non-voting representative member who is identified with industry