2009, discussing the DMAA in USP Labs' products, Mr. Patel told two of his co-conspirators, ''lol stuff is completely 100% synthethic [sic].'' From at least 2008 until at least 2013, USP Labs frequently imported other potential dietary compounds from China, under false labeling, to determine if they could be used in new dietary supplements. One of those synthetic compounds was called ''aegeline.'' The first aegeline-containing version of OxyElite Pro, which was called OxyElite ''New Formula,'' went on sale in November 2012. USP Labs reformulated the DMAA product in the summer of 2013 to contain aegeline and powder derived from a Chinese herb called cynanchum auriculatum. On or about June 15, 2013, one of Mr. Patel's co-conspirators at USP Labs instructed a Chinese company to have 2 metric tons of ground cynanchum auriculatum root powder shipped internationally to S.K. Laboratories in California for inclusion in USP Labs' products, using the false name ''cynanchum auriculatum root extract.'' USP Labs sent false labels listing ''cynanchum auriculatum (root) extract'' as an ingredient in its OxyElite Pro ''Advanced Formula'' supplement to retailers and wholesalers. On or about October 4, 2013, Mr. Patel and his co-conspirators shipped and caused the shipment of misbranded OxyElite Pro ''Advanced Formula'' into interstate commerce. The food was misbranded because its labeling falsely declared cynanchum auriculatum (root) extract as an ingredient even though it was not contained in the product.

As a result of this conviction FDA sent Mr. Patel, by certified mail on May 27, 2021, a notice proposing to debar him for a period of 5 years from importing articles of food or offering such articles for import into the United States. The proposal was based on a finding under section 306(b)(1)(C) of the FD&C Act that Mr. Patel's felony conviction of conspiracy to introduce misbranded food into interstate commerce with an intent to defraud and mislead in violation of 18 U.S.C. 371 (21 U.S.C. 331(a) and 333(a)(2)) constitutes conduct relating to the importation into the United States of an article of food because Mr. Patel was engaged in a conspiracy with others to import a variety of potential dietary compounds from a Chinese company as prospective and actual ingredients for use in dietary supplements, and instructed and agreed to have those powders labeled falsely as other food substances. The proposal was also based on a determination, after consideration of the relevant factors set forth in section 306(c)(3) of the FD&C Act, that Mr. Patel should be subject to a 5-year period of debarment. The proposal also offered Mr. Patel an opportunity to request a hearing, providing Mr. Patel 30 days from the date of receipt of the letter in which to file the request, and advised Mr. Patel that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Mr. Patel failed to respond 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)(1)(C) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Mr. Sitesh Bansi Patel has been convicted of a felony count under Federal law for conduct relating to the importation into the United States of an article of food and that he is subject to a 5-year period of debarment.

As a result of the foregoing finding, Mr. Patel is debarred for a period of 5 years from importing articles of food or offering such articles for import 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 an article of food by, with the assistance of, or at the direction of Mr. Sitesh Bansi Patel is a prohibited act.

Any application by Mr. Patel for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA–2021–N–0269 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: September 27, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–21375 Filed 9–30–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2020–N–2231; FDA–2011–N–0362; FDA–2018–N–0073; FDA–2018–N–0074; FDA–2010–N–0155; FDA–2011–N–0781; FDA–2021–N–0525; FDA–2014–N–0987; FDA–2020–N–1657; FDA–2017–N–6931; FDA–2020–N–2217; FDA–2012–N–0369; FDA–2017–N–6730; FDA–2020–N–1207; FDA–2012–N–0115; FDA–2021–N–0363; FDA–2009–N–0025; FDA–2012–N–0547; FDA–2014–N–2347; FDA–2018–N–1129; FDA–2021–N–0387; FDA–2020–N–1261; and FDA–2020–N–1644]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at *https://www.reginfo.gov/public/do/PRAMain.* 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.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
Blood Establishment Registration and Product Listing for Manufacturers of Blood and Blood Products and Licensed Devices	0910–0052	7/31/2024
Current Good Manufacturing Practice: Manufacturing, Processing, Packing, and Holding of Drugs; GMP for Finished Pharmaceuticals (Including Gases and Active Pharmaceutical Ingredients)	0910–0139	7/31/2024
Irradiation in the Production, Processing, and Handling of Food	0910–0186	7/31/2024
State Enforcement Notifications	0910–0275	7/31/2024
Veterinary Feed Directive	0910–0363	7/31/2024
Record Retention Requirements for the Soy Protein/Coronary Heart Disease Health Claim	0910–0428	7/31/2024
Prescription Drug Marketing: Administrative Procedures, Policies, and Requirements	0910–0435	7/31/2024
Generic Clearance for the Collection of Qualitative Data on Tobacco Products and Communications	0910–0796	7/31/2024
Survey of Drug Product Manufacturing, Processing, and Packing Facilities	0910–0899	7/31/2024
Current Good Manufacturing Practices for Blood and Related Regulations for Blood Components; and Requirements for Donor Testing, Donor Notification and ''Lookback''	0910–0116	8/31/2024
New Animal Drugs for Investigational Use	0910–0117	8/31/2024
Regulations Under the Federal Import Milk Act	0910–0212	8/31/2024
Medical Device Reporting	0910–0437	8/31/2024
New Plant Varieties Intended for Food Use	0910–0583	8/31/2024
Guidance for Industry and FDA Staff; Class II Special Controls: Automated Blood Cell Separator Device Operating by Centrifugal or Filtration Separation Principle	0910–0594	8/31/2024
Prescription Drug Advertisements	0910–0686	8/31/2024
Animal Food Labeling; Declaration of Certifiable Color Additives	0910–0721	8/31/2024
Survey on the Occurrence of Foodborne Illness Risk Factors in Selected Retail and Food Service Facility Types	0910–0744	8/31/2024
Food and Cosmetic Export Certificates	0910–0793	8/31/2024
National Agriculture and Food Defense Strategy Survey	0910–0855	8/31/2024
Medical Product Communications That are Consistent With the Food and Drug Administration Required Labeling—Questions and Answers	0910–0856	8/31/2024
Drug and Device Manufacturer Communications with Payors, Formulary Committees, and Similar Entities Questions and Answers	0910–0857	8/31/2024
Study of Disclosures to Health Care Providers Regarding Data That Do Not Support Unapproved Use of an Approved Prescription Drug	0910–0900	8/31/2024
Medical Conference Attendees' Observations About Prescription Drug Promotion	0910–0901	8/31/2024

Dated: September 24, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–21386 Filed 9–30–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Final Policy: Updates to Uniform Standard for Waiver of the Ryan White HIV/AIDS Program Core Medical Services Expenditure Requirement

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice of final policy.

SUMMARY: The Ryan White HIV/AIDS Program (RWHAP) statute of the Public Health Services Act requires that RWHAP Part A, B, and C recipients expend not less than 75 percent of Parts A, B, and C grant funds on core medical services for individuals with HIV/AIDS identified and eligible under the statute, after reserving statutory permissible amounts for administrative and clinical quality management (CQM) costs. The statute also grants the Secretary of HHS authority to waive this requirement if certain requirements are met. HRSA has simplified the process for RWHAP Part A, B, and C recipients to request a waiver of the core medical services expenditure amount requirement by replacing HRSA Policy Number 13–07, ''Uniform Standard for Waiver of Core Medical Services Requirement for Grantees Under Parts, A, B, and C'' with Policy Notice 21–01, ''Waiver of the Ryan White HIV/AIDS Program Core Medical Services Expenditure Requirement.''

DATES: The final policy is effective on October 1, 2021.

FOR FURTHER INFORMATION CONTACT: Lieutenant Commander Emeka Egwim, U.S. Public Health Service, Senior Policy Analyst, Division of Policy & Data, HRSA, HIV/AIDS Bureau, 5600 Fishers Lane, Rockville, MD 20857, Phone: (301) 945–9637 or by emailing *RWHAPPolicy@hrsa.gov.* When requesting information, please include this **Federal Register** notice title for reference.

SUPPLEMENTARY INFORMATION: The RWHAP statute also grants the Secretary of HHS authority to waive this requirement for RWHAP Parts A, B, or C recipients if a number of requirements are met and a waiver request is submitted to HRSA for approval. RWHAP Part A, B, and C core medical services waiver requests—if approved—are effective for a 1-year budget period, and apply to funds awarded under the Minority AIDS Initiative.

Currently, for a core medical services waiver request to be approved, (1) core medical services must be available and accessible to all individuals identified and eligible for the RWHAP in the recipient's service area within 30 days, without regard to payer source; (2) there cannot be any AIDS Drug Assistance Program (ADAP) waiting lists in the recipient's service area; and (3) a public process to obtain input on the waiver request from impacted communities, including clients and RWHAP-funded core medical services providers, on the availability of core medical services and the decision to request the waiver must have occurred. The public process may be a part of the same one used to seek input on community needs as part of the annual priority setting and resource allocation, comprehensive planning, statewide coordinated statement of