• *Confidential Submissions*—To submit an application with confidential information that you do not wish to be made publicly available, submit your application 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 your application. 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 application 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, 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 between 9 a.m. and 4 p.m., Monday through Friday. Publicly available submissions may be seen in the docket.

FOR FURTHER INFORMATION CONTACT: Julie Finegan, Office of Scientific Integrity, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4218, Silver Spring, MD 20993, 301–796–8618.

SUPPLEMENTARY INFORMATION:

I. Background

On June 24, 2013, the U. S. District Court for the Eastern District of Tennessee entered a criminal judgment against William Ralph Kincaid pursuant to his guilty plea. Kincaid pled guilty to a felony under the FD&C Act, namely receiving in interstate commerce a misbranded drug with intent to defraud or mislead, in violation of sections 301(c) and 303(a)(2) of the FD&C Act (21 U.S.C. 331(c) and 333(a)(2)) and 18 U.S.C. 2. The basis for this conviction was Kincaid's admission that he obtained drugs from Quality Specialty Products (QSP), a foreign company, for use at East Tennessee Hematology-Oncology Associates, P.C. (McLeod Cancer). These drugs were not FDA approved and were misbranded in that they lacked adequate directions for use and were manufactured in an establishment that was not registered with FDA and that did not list with FDA the drug products it manufactured. From approximately September 2007 to early 2008 and from August 2009 to February 2012, McLeod Cancer purchased more than $2 million in misbranded unapproved drugs for use at McLeod Cancer. Additionally, Kincaid and McLeod Cancer billed Medicare, TennCare, and other government health benefit programs approximately $2.5 million for these unapproved drugs.

Kincaid is subject to debarment based on a finding, under section 306(a)(2) of the FD&C Act (21 U.S.C. 335a(a)(2)), that he was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. By the letter dated May 20, 2015, FDA notified Kincaid of a proposal to permanently debar him from providing services in any capacity to a person having an approved or pending drug product application. The proposal also offered Kincaid 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 60 days from the date of receipt of the letter to support that request with information sufficient to justify a hearing. In a letter dated June 17, 2015, Kincaid requested a hearing and indicated that the information justifying the hearing would be forthcoming. More than 60 days have passed from the date Kincaid received FDA's letter, and Kincaid has not filed any additional information to support his request.

Under the authority delegated to him by the Commissioner of Food and Drugs, the Director of the Office of Scientific Integrity (OSI) has considered Kincaid's request for a hearing. Hearings will not be granted on issues of policy or law, on mere allegations, denials, or general descriptions of positions and contentions, or on data and information insufficient to justify the factual determination urged (see 21 CFR 21.24(b)).

Because Kincaid has not presented any information to support his hearing request, OSI concludes that Kincaid failed to raise a genuine and substantial issue of fact requiring a hearing. Therefore, OSI denies Kincaid's request for a hearing.

II. Findings and Order

Therefore, OSI, under section 306(a)(2) of the FD&C Act and under the authority delegated, finds that William Ralph Kincaid has been convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act.

As a result of the foregoing findings, William Ralph Kincaid is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under section 505, 512, or 802 of the FD&C Act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective (see **DATES**) (21 U.S.C. 335a(c)(1)(B) and (c)(2)(A)(ii) and 21 U.S.C. 321(dd)). Any person with an approved or pending drug product application who knowingly uses the services of Kincaid, in any capacity during his period of debarment, will be subject to civil money penalties. See section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6)). If Kincaid, during his period of debarment, provides services in any capacity to a person with an approved or pending drug product application, he will be subject to civil money penalties. See section 307(a)(7) of the FD&C Act (21 U.S.C. 335b(a)(7)). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Kincaid during his period of debarment.

Dated: January 10, 2018.

G. Matthew Warren,

Director, Office of Scientific Integrity.

[FR Doc. 2018–00719 Filed 1–17–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Annual Update of the HHS Poverty Guidelines

AGENCY: Department of Health and Human Services.

ACTION: Notice.

SUMMARY: This notice provides an update of the Department of Health and Human Services (HHS) poverty guidelines to account for last calendar year's increase in prices as measured by the Consumer Price Index.

DATES: Applicable beginning January 13, 2018, unless an office administering a program using the guidelines specifies a different applicability date for that particular program.

ADDRESSES: Office of the Assistant Secretary for Planning and Evaluation, Room 404E, Humphrey Building, Department of Health and Human Services, Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: For information about how the guidelines are used or how income is defined in a particular program, contact the Federal, state, or local office that is responsible for that program. For information about poverty figures for immigration forms, the Hill-Burton Uncompensated Services Program, and the number of people in poverty, use the specific telephone numbers and addresses given below.

For general questions about the poverty guidelines themselves, contact Kendall Swenson, Office of the Assistant Secretary for Planning and Evaluation, Room 422F.5, Humphrey Building, Department of Health and Human Services, Washington, DC 20201—telephone: (202) 690–7409—or visit *http://aspe.hhs.gov/poverty/.*

For information about the percentage multiple of the poverty guidelines to be used on immigration forms such as USCIS Form I–864, Affidavit of Support, contact U.S. Citizenship and Immigration Services at 1–800–375–5283.

For information about the Hill-Burton Uncompensated Services Program (free or reduced-fee health care services at certain hospitals and other facilities for persons meeting eligibility criteria involving the poverty guidelines), contact the Health Resources and Services Administration Information Center at 1–800–275–4772. You also may visit *https://www.hrsa.gov/get-health-care/affordable/hill-burton/index.html.*

For information about the number of people in poverty, visit the Poverty section of the Census Bureau's website at *https://www.census.gov/topics/income-poverty/poverty.html* or contact the Census Bureau's Customer Service Center at 1–800–923–8282 (toll-free) or visit *https://ask.census.gov* for further information.

SUPPLEMENTARY INFORMATION:

Background

Section 673(2) of the Omnibus Budget Reconciliation Act (OBRA) of 1981 (42 U.S.C. 9902(2)) requires the Secretary of the Department of Health and Human Services to update the poverty guidelines at least annually, adjusting them on the basis of the Consumer Price Index for All Urban Consumers (CPI–U). The poverty guidelines are used as an eligibility criterion by Medicaid and a number of other Federal programs. The *poverty guidelines* issued here are a simplified version of the *poverty thresholds* that the Census Bureau uses to prepare its estimates of the number of individuals and families in poverty.

As required by law, this update is accomplished by increasing the latest published Census Bureau poverty thresholds by the relevant percentage change in the Consumer Price Index for All Urban Consumers (CPI–U). The guidelines in this 2018 notice reflect the 2.1 percent price increase between calendar years 2016 and 2017. After this inflation adjustment, the guidelines are rounded and adjusted to standardize the differences between family sizes. In rare circumstances, the rounding and standardizing adjustments in the formula result in small decreases in the poverty guidelines for some household sizes even when the inflation factor is not negative. In cases where the year-to-year change in inflation is not negative and the rounding and standardizing adjustments in the formula result in reductions to the guidelines from the previous year for some household sizes, the guidelines for the affected household sizes are fixed at the prior year's guidelines. As in prior years, these 2018 guidelines are roughly equal to the poverty thresholds for calendar year 2017 which the Census Bureau expects to publish in final form in September 2018.

The poverty guidelines continue to be derived from the Census Bureau's current official poverty thresholds; they are not derived from the Census Bureau's Supplemental Poverty Measure (SPM).

The following guideline figures represent annual income.

2018 Poverty Guidelines for the 48 Contiguous States and the District of Columbia

Persons in family/household	Poverty guideline
1	$12,140
2	16,460
3	20,780
4	25,100
5	29,420
6	33,740
7	38,060
8	42,380

For families/households with more than 8 persons, add $4,320 for each additional person.

2018 Poverty Guidelines for Alaska

Persons in family/household	Poverty guideline
1	$15,180
2	20,580
3	25,980
4	31,380
5	36,780
6	42,180
7	47,580
8	52,980

For families/households with more than 8 persons, add $5,400 for each additional person.

2018 Poverty Guidelines for Hawaii

Persons in family/household	Poverty guideline
1	$13,960
2	18,930
3	23,900
4	28,870
5	33,840
6	38,810
7	43,780
8	48,750

For families/households with more than 8 persons, add $4,970 for each additional person.

Separate poverty guideline figures for Alaska and Hawaii reflect Office of Economic Opportunity administrative practice beginning in the 1966–1970 period. (Note that the Census Bureau poverty thresholds—the version of the poverty measure used for statistical purposes—have never had separate figures for Alaska and Hawaii.) The poverty guidelines are not defined for Puerto Rico or other outlying jurisdictions. In cases in which a Federal program using the poverty guidelines serves any of those jurisdictions, the Federal office that administers the program is generally responsible for deciding whether to use the contiguous-states-and-DC guidelines for those jurisdictions or to follow some other procedure.

Due to confusing legislative language dating back to 1972, the poverty guidelines sometimes have been mistakenly referred to as the ''OMB'' (Office of Management and Budget) poverty guidelines or poverty line. In fact, OMB has never issued the guidelines; the guidelines are issued each year by the Department of Health and Human Services. The poverty guidelines may be formally referenced as ''the poverty guidelines updated periodically in the **Federal Register** by

the U.S. Department of Health and Human Services under the authority of 42 U.S.C. 9902(2).''

Some federal programs use a percentage multiple of the guidelines (for example, 125 percent or 185 percent of the guidelines), as noted in relevant authorizing legislation or program regulations. Non-Federal organizations that use the poverty guidelines under their own authority in non-Federally-funded activities also may choose to use a percentage multiple of the guidelines.

The poverty guidelines do not make a distinction between farm and non-farm families, or between aged and non-aged units. (Only the Census Bureau poverty thresholds have separate figures for aged and non-aged one-person and two-person units.)

Note that this notice does not provide definitions of such terms as ''income'' or ''family,'' because there is considerable variation in defining these terms among the different programs that use the guidelines. These variations are traceable to the different laws and regulations that govern the various programs. This means that questions such as ''Is income counted before or after taxes?'', ''Should a particular type of income be counted?'', and ''Should a particular person be counted as a member of the family/household?'' are actually questions about how a specific program applies the poverty guidelines. All such questions about how a specific program applies the guidelines should be directed to the entity that administers or funds the program, since that entity has the responsibility for defining such terms as ''income'' or ''family,'' to the extent that these terms are not already defined for the program in legislation or regulations.

Dated: January 12, 2018.

Eric D. Hargan,

Acting Secretary of Health and Human Services.

[FR Doc. 2018–00814 Filed 1–12–18; 4:15 pm]

BILLING CODE 4150–05–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Automated Commercial Environment (ACE) Becoming the Sole CBP-Authorized Electronic Data Interchange (EDI) System for Processing Electronic Drawback Filings

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: General notice.

SUMMARY: This document announces that the Automated Commercial Environment (ACE) will be the sole electronic data interchange (EDI) system authorized by U.S. Customs and Border Protection (CBP) for processing electronic drawback filings under part 181 (NAFTA drawback) and part 191 (non-TFTEA drawback) of Title 19 of the Code of Federal Regulations. This document also announces that the Automated Commercial System (ACS) will no longer be a CBP-authorized EDI system for purposes of processing such filings. This notice further announces the deployment of a new ACE filing code for all electronic drawback filings, replacing the six distinct drawback codes previously filed in ACS.

DATES: As of February 24, 2018, ACE will be the sole CBP-authorized EDI system for processing drawback filings under part 181 (NAFTA drawback) and part 191 (non-TFTEA drawback) of Title 19 of the Code of Federal Regulations, and ACS will no longer be a CBP-authorized EDI system for such purpose.

FOR FURTHER INFORMATION CONTACT: Randy Mitchell, Commercial Operations and Entry Division, Trade Policy and Programs, Office of Trade at (202) 863–6532 or *RANDY.MITCHELL@CBP.DHS.GOV.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 484 of the Tariff Act of 1930, as amended (19 U.S.C. 1484), establishes the requirement for importers of record to make entry for merchandise to be imported into the customs territory of the United States. Customs entry information is used by U.S. Customs and Border Protection (CBP) and Partner Government Agencies (PGAs) to determine whether merchandise may be released from CBP custody. Importers of record are also obligated to complete the entry by filing an entry summary declaring the value, classification, rate of duty applicable to the merchandise and such other information as is necessary for CBP to properly assess duties, collect accurate statistics and determine whether any other applicable requirement of law is met.

The customs entry requirements were amended by Title VI of the North American Free Trade Agreement Implementation Act (Pub. L. 103–182, 107 Stat. 2057, December 8, 1993), commonly known as the Customs Modernization Act, or Mod Act. In particular, section 637 of the Mod Act amended section 484(a)(1)(A) of the Tariff Act of 1930 (19 U.S.C. 1484(a)(1)(A)) by revising the requirement to make and complete customs entry by submitting documentation to CBP to allow, in the alternative, the electronic transmission of such entry information pursuant to a CBP-authorized electronic data interchange (EDI) system. CBP created the Automated Commercial System (ACS) to track, control, and process all commercial goods imported into the United States. CBP established the specific requirements and procedures for the electronic filing of entry and entry summary data for imported merchandise through the Automated Broker Interface (ABI) to ACS.

II. Transition Into the Automated Commercial Environment

In an effort to modernize the business processes essential to securing U.S. borders, facilitating the flow of legitimate shipments, and targeting illicit goods pursuant to the Mod Act and the Security and Accountability for Every (SAFE) Port Act of 2006 (Pub. L. 109–347, 120 Stat. 1884), CBP developed the Automated Commercial Environment (ACE) to eventually replace ACS as the CBP-authorized EDI system. Over the last several years, CBP has tested ACE and provided significant public outreach to ensure that the trade community is fully aware of the transition from ACS to ACE.

On October 13, 2015, CBP published an Interim Final Rule in the **Federal Register** (80 FR 61278) that designated ACE as a CBP-authorized EDI system. The designation of ACE as a CBP-authorized EDI system was effective November 1, 2015. In the Interim Final Rule, CBP stated that ACS would be phased out and anticipated that ACS would no longer be supported for entry and entry summary filing. Filers were encouraged to adjust their business practices so that they would be prepared when ACS was decommissioned.

CBP developed a staggered transition strategy for decommissioning ACS. The phases of the transition were announced in several **Federal Register** notices. *See* 81 FR 10264 (February 29, 2016); 81 FR 30320 (May 16, 2016); 81 FR 32339 (May 23, 2016); 82 FR 38924 (August 16, 2017); and 82 FR 51852 (November 8, 2017). This notice announces another transition as the processing of electronic drawback filings under parts 181 and 191 of title 19 of the Code of Federal Regulations (CFR) is transitioning into ACE.