Transitional Grant Areas (TGAs). As a component of Part A (previously Title I), the purpose of the Minority AIDS Initiative (MAI) Supplement is to improve access to high quality HIV care services and health outcomes for individuals in disproportionately impacted communities of color who are living with HIV disease, including African-Americans, Latinos, Native Americans, Alaska Natives, Asian Americans, Native Hawaiians and Pacific Islanders (Section 2693(b)(2)(A) of the Public Health Service (PHS) Act). Since the purpose of the Part A MAI is to expand access to medical, health, and social support services for disproportionately impacted racial/ethnic minority populations living with HIV/AIDS, who are not yet in care, it is important that HRSA is able to report on minorities served by the Part A MAI.

The Part A MAI Report is a data collection instrument in which grantees report on the number and characteristics of clients served and services provided. The *Part A MAI Report,* first approved for use in March 2006, is designed to collect performance data from Part A Grantees that will not change, and it has two parts: (1) A Web-based data entry application that collects standardized quantitative and qualitative information, and (2) an accompanying narrative report.

Grantees submit two *Part A MAI Reports* annually: *Part A MAI Plan* (*Plan*) and the *Part A MAI Year-End Annual Report* (*Annual Report*). The *Plan* and *Annual Report* components of the report are linked to minimize the reporting burden, and include drop-down menu responses, fields for reporting budget, expenditure and aggregated client level data, and open-ended responses for describing client or service-level outcomes. Together the *Plan* and *Annual Report* components collect information from grantees on MAI-funded services, expenditure patterns, the number and demographics of clients served, and client-level outcomes.

The MAI *Plan* Narrative that accompanies the *Plan* Web-forms provides (1) an explanation of the data submitted in the *Plan* Web forms; (2) a summary of the *Plan,* including the plan and timeline for disbursing funds, monitoring service delivery, and implementing any service-related capacity development or technical assistance activities; and (3) the plan and timeline for documenting client-level outcome measures. In addition, if the EMA/TGA revised any planned services, allocation amounts or target communities after their grant application was submitted, the changes must be highlighted and explained. The accompanying MAI *Annual Report* Narrative describes (1) progress towards achieving specific goals and objectives identified in the Grantee's approved *MAI Plan* for that fiscal year and in linking MAI services/activities to Part A and other Ryan White HIV/AIDS Program services; (2) achievements in relation to client-level health outcomes; (3) summary of challenges or barriers at the provider or grantee levels, the strategies and/or action steps implemented to address them, and lessons learned; and (4) discussion of MAI technical assistance needs identified by the EMA/TGA.

This information is needed to monitor and assess: (1) Changes in the type and amount of HIV/AIDS health care and related services being provided to each disproportionately impacted community of color; (2) the aggregate number of persons receiving HIV/AIDS services within each racial and ethnic community; and (3) the impact of Part A MAI-funded services in terms of client-level and service-level health outcomes. The information also is used to plan new technical assistance and capacity development activities and inform the HRSA policy and program management functions. The data provided to HRSA does not contain individual or personally identifiable information.

The annual estimated response burden for grantees is as follows:

Form	Estimated number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Part A MAI Report	56	2	112	5 hrs	560

Note: Data collection system enhancements have resulted in a shortened response burden (from 6 to 5 total hours per response) for respondents since the previous OMB approval request.

E-mail comments to *paperwork@hrsa.gov* or mail the HRSA Reports Clearance Officer, Room 10–33, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857. Written comments should be received within 60 days of this notice.

Dated: January 6, 2010.

Sahira Rafiullah,

Deputy Director, Division of Policy Review and Coordination.

[FR Doc. 2010–364 Filed 1–11–10; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0305]

Jason Vale; Denial of Hearing; Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is denying Jason Vale's request for a hearing and is issuing an order under the Federal Food, Drug, and Cosmetic Act (the act) permanently debarring Mr. Vale 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. Vale was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the act. Mr. Vale has failed to file with the agency information and analyses sufficient to create a basis for a hearing concerning this action.

DATES: The order is effective January 12, 2010.

ADDRESSES: Submit applications for termination of debarment to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: G. Matthew Warren, Office of Scientific Integrity, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–4613.

SUPPLEMENTARY INFORMATION:

I. Background

On July 21, 2003, a Federal jury found Mr. Vale, formerly the president of Christian Brother's Inc., guilty of three counts of criminal contempt in violation of 18 U.S.C. 401(3). On June 18, 2004, the U.S. District Court for the Eastern District of New York sentenced Mr. Vale to 63 months in prison on each of the three counts, to be served concurrently. On January 26, 2006, on remand from the Court of Appeals for the Second Circuit, the district court reduced the sentence to 60 months.

Mr. Vale is subject to permanent debarment based on a finding, under section 306(a)(2) of the 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. Mr. Vale's convictions for contempt stemmed from his violation of consent decrees of preliminary and permanent injunction prohibiting him from distributing unapproved or misbranded drugs, including any drugs or other products, containing or purporting to contain, Laetrile, "Vitamin B–17," amygdalin, or apricot seeds. The evidence introduced at Mr. Vale's criminal contempt trial showed that, in violation of the two injunctions, he continued to promote and sell amygdalin-based products and apricot seeds under a different business name. Mr. Vale acquired a post office box in Arizona under the name "Praise Distributing" (Praise), began referring former and incoming customers of Christian Brothers to a Praise phone number for purchase of those products, and continued to sell those products to his customers through Praise, with the assistance of others employed by Christian Brothers. Mr. Vale's convictions for criminal contempt under 18 U.S.C. 401(3) related directly to the regulation of drug products under the act. By continuing to market amygdalin-based products and apricot seeds, Mr. Vale ignored two injunctions, which were intended to prevent him from violating the requirements for drug products in the act.

By letter dated June 26, 2008, FDA served Mr. Vale a notice proposing to permanently debar him from providing services in any capacity to a person having an approved or pending drug product application. In a letter dated August 13, 2008, Mr. Vale requested a hearing on the proposal. In his request for a hearing, Mr. Vale acknowledges his convictions under Federal law, as alleged by FDA. However, he argues that his convictions for criminal contempt under 18 U.S.C. 401(3) are not felony convictions subjecting him to permanent debarment under section 306(a)(2) of the act.

We reviewed Mr. Vale's request for a hearing and find that Mr. Vale has not created a basis for a hearing because hearings will be granted only if there is a genuine and substantial issue of fact. 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 12.24(b)).

The Acting Chief Scientist and Deputy Commissioner has considered Mr. Vale's arguments and concludes that they are unpersuasive and fail to raise a genuine and substantial issue of fact requiring a hearing.

II. Argument

Mr. Vale raises a single legal argument in support of his hearing request. Citing *Frank* v. *United States*, 395 U.S. 147, 149–52 (1969), he contends that his convictions for criminal contempt under 18 U.S.C. 401(3) may not be characterized as felony convictions for purposes of section 306(a)(2) of the act because criminal contempt is not a felony under Federal law. An offense is typically a felony if the maximum term authorized is more than 1 year. (*See* 18 U.S.C. 3559(a)(1)–(5) (categorizing offenses as felonies if maximum terms of imprisonment are greater than 1 year); *United States* v. *Wildes*, 120 F.3d 468, 470 (4th Cir. 1997) (relying on 18 U.S.C. 3559 to conclude that a felony is any offense punishable by more than one year in prison)). Under 18 U.S.C. 401, however, there is no specific term of imprisonment authorized; a Federal court has the power to punish criminal contempt by imprisonment "at its discretion."

In *Frank*, the U.S. Supreme Court addressed whether a particular offense under 18 U.S.C. 401 was "petty" or "serious" for purposes of the criminal contemnor's right to a jury trial under the Sixth Amendment. (395 U.S. at 148–52.) The Supreme Court acknowledged that criminal contempt is a *sui generis* offense (id. at n.5, citing *Cheff* v. *Schnackenberg*, 384 U.S. 373, 379–80 (1966)) in that "a person may be found in contempt for a great many different types of offenses, ranging from disrespect for the court to acts otherwise criminal." (*Frank*, 395 U.S. at 149.) But the Court found that "in prosecutions for criminal contempt where no maximum penalty is authorized, the severity of the penalty actually imposed is the best indication of the seriousness of the particular offense." (Id.) The Court concluded that the particular offense at issue was "petty" because the contemnor received less than 6 months in prison. (Id. at 152)

In short, the Supreme Court held in *Frank* that, when sentence has been imposed, the length of that sentence is an appropriate measure for determining whether a criminal contempt conviction is a petty offense, misdemeanor, or felony.[1] FDA will therefore look to the sentence imposed on Mr. Vale upon his conviction to evaluate whether his offense under 18 U.S.C. 401(3) was a felony. At 5 years for each conviction, Mr. Vale's sentences far exceeded 1 year, and thus his convictions were clearly for felony offenses. Accordingly, FDA concludes that all three of his convictions of criminal contempt subject him to mandatory debarment under section 306(a)(2) of the act.

III. Findings and Order

Therefore, the Acting Chief Scientist and Deputy Commissioner, under section 306(a)(2)(B) of the act and under authority delegated to him, finds that Mr. Vale has been convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the act.

As a result of the foregoing findings, Mr. Vale 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 act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), (see **DATES**) (see section 306(c)(1)(B) and (c)(2)(A)(ii) and section 201(dd) of the act (21 U.S.C. 321(dd))). Any person with an approved or pending drug product application who knowingly uses the services of Mr. Vale, in any capacity during his period of debarment, will be subject to civil money penalties. If Mr. Vale, during his period of debarment, provides services in any capacity to a person with an

[1] There is, however, a split among the Federal Circuits with respect to whether a conviction for criminal contempt may be treated as a felony. The Court of Appeals for the Fifth Circuit has read the Supreme Court's decisions in *Frank* and *Cheff* to mean that criminal contempt can never be a felony. (*United States* v. *Holmes*, 822 F.2d 481, 493–94 (5th Cir. 1987) (citing those cases for the proposition that criminal contempt is neither a misdemeanor nor a felony)). The Court of Appeals for the Ninth Circuit, however, has relied on the decision in *Frank* to conclude that a conviction of criminal contempt may be treated as a felony based on the defendant's sentencing range. (*United States* v. *Carpenter*, 91 F.3d 1282, 1283–86 (9th Cir. 1996) (holding that courts should look to the appropriate sentencing guideline range to determine whether a particular offense under 18 U.S.C. 401 is a felony); see also In re *Cohn*, 525 F.Supp.2d 1316, 1321 (S.D.Fla. 2007) (holding that criminal contempt is always a Class A felony under 18 U.S.C. 3559(a) because the maximum sentence is life in prison)).

approved or pending drug product application, he will be subject to civil money penalties. In addition, FDA will not accept or review any ANDAs submitted by or with the assistance of Mr. Vale during his period of debarment.

Any application by Mr. Vale for termination of debarment under section 306(d)(4) of the act should be identified with Docket No. FDA–2008–N–0305 and sent to the Division of Dockets Management (see **ADDRESSES**). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20(j). Publicly available submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 4, 2010.

Jesse L. Goodman,

Acting Chief Scientist and Deputy Commissioner for Science and Public Health.

[FR Doc. 2010–289 Filed 1–11–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Privacy Act of 1974; Report of Amended or Altered System; Medical, Health and Billing Records System

AGENCY: Indian Health Service (IHS), HHS.

ACTION: Amendment of One Altered Privacy Act System of Records (PASOR), 09–17–0001.

SUMMARY: Pursuant to the provisions of the Privacy Act of 1974, as amended, 5 U.S.C. 552a(e)(4), the IHS has amended and is publishing the proposed alteration of a system of records, System No. 09–17–0001, "Medical, Health and Billing Records." The amended and altered system of records is to reflect revisions in the Purpose and Routine Uses sections, the Notification Procedures section and updates to Appendix 1 of the PASOR.

In the Purpose section of the PASOR, IHS is altering number seven to allow the disclosure of controlled substance prescription data and/or protected health information (PHI) and personally identifiable information (PII) to its business associate contractor(s) for stated healthcare operations prior to transferring to various State Health Monitoring Programs and Registries; and to disclose data transmission of PHI to various health data exchange, regional health information and e-prescribing networks.

In the Routine Uses section, routine use number thirteen is altered to include language that will allow the disclosure to various stated healthcare operations and health data exchange, regional health information and e-prescribing networks.

In the Notification Procedure section under Record Access and Contesting Record procedures, IHS is referencing its various IHS forms with its stated purposes to be utilized by the requester(s).

DATES: *Effective Dates:* IHS filed an altered system report with the Chair of the House Committee on Oversight and Government Reform, the Chair of the Senate Committee on Homeland Security and Governmental Affairs, and the Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) on January 12, 2010. To ensure that all parties have adequate time in which to comment, the altered PASOR will become effective 40 days from the publication of the notice, or from the date the SOR was submitted to OMB and the Congress, whichever is later, unless IHS receives comments on all portions of this notice.

ADDRESSES: The public should address comments to: Mr. William Tibbitts, IHS Privacy Act Officer, Division of Regulatory Affairs, Office of Management Services, 801 Thompson Avenue, TMP, Suite 450, Rockville, MD 20852–1627; call non-toll free (301) 443–1116; send via facsimile to (301) 443–9879, or send your e-mail requests, comments, and return address to: *William.Tibbitts@ihs.gov.*

FOR FURTHER INFORMATION CONTACT: Ms. Patricia Gowan, IHS Lead Health Information Management (HIM) Consultant and Area HIM Consultants, Office of Health Programs, Phoenix Area Office, Two Renaissance Square, Suite 606, 40 North Central Avenue, Phoenix, AZ 85004–4450, Telephone (602) 364–5172 or via the Internet at *Patricia.Gowan@ihs.gov.*

SUPPLEMENTARY INFORMATION: As required by the Privacy Act of 1974, as amended, 5 U.S.C. 552a(e)(4), this document sets forth the amendment of the proposed alteration of a system of records maintained by the IHS. IHS is altering System No. 09–17–0001, "Health, Medical and Billing Records," for the stated reasons. First, a change to the Purpose section number seven will further enable IHS to disclose controlled substance prescription data to a business associate contractor(s) for stated healthcare operations prior to transferring to various State Health Monitoring Programs and Registries; as well as to enable IHS to disclose data transmission of PHI to various health data exchange and/or regional health information contractors. Second, a change to the Routine Uses section number thirteen will enable IHS to allow the disclosure of information from the record for the various stated healthcare operations and Health Data Exchange; Regional Health Information; and e-prescribing networks.

Dated: December 29, 2009.

Yvette Roubideaux,

Director, Indian Health Service.

Department of Health and Human Services

Indian Health Service

System Number: 09–17–0001

SYSTEM NAME:

Medical, Health, and Billing Records Systems, Health and Human Services/Indian Health Service/Office of Clinical and Preventive Services (HHS/IHS/OCPS).

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

IHS hospitals, health centers, school health centers, health stations, field clinics, Service Units, IHS Area Offices (Appendix 1), and Federal Archives and Records Centers (Appendix 2). Automated, electronic health and computerized records, including but not limited to clinical information and Patient Care Component (PCC) records, are stored in the Resource and Patient Management System (RPMS) at the National Programs/Office of Information Technology (NP/OIT), IHS, located in Albuquerque, New Mexico. Records may also be located at contractor sites. A current list of contractor sites is available by writing to the appropriate System Manager (Area or Service Unit Director/Chief Executive Officer) at the address shown in Appendix 1.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals, including both IHS beneficiaries and non-beneficiaries, who are examined/treated on an inpatient and/or outpatient basis by IHS staff and/or contract health care providers (including Tribal contractors).

CATEGORIES OF RECORDS IN THE SYSTEM:

Note: Records relating to claims by and against the HHS are maintained in the Privacy Act System of Records (PASOR)