Dated: October 9, 2003.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 03–26270 Filed 10–17–03; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0102]

Robert Ray Courtney; 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 (the act) permanently debarring Robert Ray Courtney 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. Courtney was convicted of a felony under Federal law for conduct otherwise relating to the regulation of any drug product under the act. Mr. Courtney failed to request a hearing and, therefore, has waived his opportunity for a hearing concerning this action.

DATES: This order is effective October 20, 2003.

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: Nicole K. Mueller, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION:

I. Background

On February 26, 2002, Mr. Robert Ray Courtney entered into an agreement pleading guilty to eight counts of tampering with consumer products in violation of 18 U.S.C. 1365(a) and (a)(3), and six counts each of misbranding and adulterating drugs in violation of sections 301(k) and 303(a)(2) of the act (21 U.S.C. 331(k) and 333(a)(2)). On December 5, 2002, the U.S. District Court for the Western District of Missouri sentenced Mr. Courtney to the maximum 30 years in prison and required Mr. Courtney to pay a fine of $25,000 and $10.4 million in restitution for diluting drugs he dispensed to his pharmacy customers. Such drugs included the chemotherapy medications Gemzar (gemcitabine) and Taxol (paclitaxel).

At the time of Mr. Courtney's criminal actions, he was a pharmacist and owner of Courtney Pharmacy, Inc., d/b/a Research Medical Tower Pharmacy, a company that operated two pharmacies: Research Medical Tower Pharmacy in Kansas City, MO, and Courtney Pharmacy in Overland Park, KS. Among other things, Mr. Courtney was responsible for mixing, preparing, labeling, and distributing intravenous drug mixtures.

In 2001, the Federal Bureau of Investigations (FBI) and FDA set up an investigation that revealed that certain medications Mr. Courtney dispensed were far less potent than the medications ordered by prescribing physicians. One drug sample contained less than 1 percent of the prescribed amount. The investigation resulted in the filing of a complaint on August 14, 2001, charging Mr. Courtney with adulteration and misbranding. It was eventually determined that more than 4,000 patients may have had their prescriptions diluted by Mr. Courtney over a 10-year period. The investigation and admissions by Mr. Courtney culminated in his guilty plea to all 20 counts of the indictment.

As a result of this conviction, FDA served Mr. Courtney by certified mail on May 16, 2003, a notice proposing to permanently debar him from providing services in any capacity to a person that has an approved or pending drug product application. The proposal also offered Mr. Courtney an opportunity for a hearing on the proposal. The proposal was based on a finding, under section 306(a)(2)(B) of the act (21 U.S.C. 335a(a)(2)(B)), that Mr. Courtney was convicted of a felony under Federal law for conduct otherwise relating to the regulation of any drug product under the act. Mr. Courtney was provided 30 days to file objections and request a hearing. Mr. Courtney did not request a hearing. His failure to request a hearing constitutes a waiver of his opportunity for a hearing and a waiver of any contentions concerning his debarment.

II. Findings and Order

Therefore, the Director, Center for Drug Evaluation and Research, under section 306(a)(2)(B) of the act, and under authority delegated to her (21 CFR 5.34), finds that Mr. Robert Ray Courtney has been convicted of a felony under Federal law for conduct otherwise relating to the regulation of any drug product under the act.

As a result of the foregoing finding, Mr. Robert Ray Courtney is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under sections 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), effective October 20, 2003 (see sections 306(c)(1)(B) and (c)(2)(A)(ii) and 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. Courtney, in any capacity, during his period of debarment, will be subject to civil money penalties (section 307(a)(6) of the act (21 U.S.C. 335b(a)(6))). If Mr. Courtney, 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 (section 307(a)(7) of the act). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Mr. Courtney during his period of debarment.

Any application by Mr. Courtney for termination of debarment under section 306(d)(4) of the act should be identified with Docket No. 03N–0102 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 1, 2003.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 03–26385 Filed 10–17–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Factor VIII Inhibitors; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled ''Factor VIII Inhibitors.'' The purpose of the public workshop is to provide a forum for addressing

regulatory and scientific concerns about inhibitors to Factor VIII, one of the components of blood necessary for clotting, with regard to inhibitor antibodies in Factor VIII products.

Date and Time: The workshop will be held on November 21, 2003, from 8 a.m. to 5 p.m.

Location: The workshop will be held at Lister Hill Auditorium, Bldg. 38A, National Institutes of Health, 8600 Rockville Pike, Bethesda, MD 20894.

Contact Person: Joseph Wilczek, Center for Biologics Evaluation and Research (HFM–302), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6129, FAX: 301–827–2843, e-mail: *wilczek@cber.fda.gov.*

Registration: Send registration information (including name, title, firm name, address, telephone, and fax number) to the contact person by November 7, 2003. Early registration is recommended because seating is limited to 176 participants. Registration will be done on a space available basis on the day of the workshop, beginning at 7:15 a.m. There is no registration fee.

If you need special accommodations due to a disability, please contact Joseph Wilczek (see *Contact Person*) at least 7 days in advance.

Transcripts: Transcripts of the workshop may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page. In addition, the transcript will be placed on the FDA Web site at *http://www.fda.gov/cber/minutes/workshop-min.htm.*

SUPPLEMENTARY INFORMATION: FDA and the International Association for Biologicals (IABs) are co-sponsoring a public workshop on regulatory and scientific concerns pertaining to the potential immunogenicity of Factor VIII products. The purpose of the workshop is to provide a forum for discussion of the inhibitor phenomenon with respect to currently available products and products that are under development by various sponsors. National and international regulatory authorities, manufacturers, clinicians, and academics will discuss their experiences with this issue regarding preclinical testing requirements, the results of clinical trials, and post-marketing surveillance. Other issues to be discussed at the workshop include properties of Factor VIII inhibitor assays, epidemiological aspects of inhibitor formation, and the design of prospective clinical studies. The public workshop agenda is posted on the FDA Internet at *http://www.fda.gov/cber/meetings/fctrviii112103.htm.*

Dated: October 10, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–26386 Filed 10–17–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

[HRSA–04–030]

Amendment to a Notice of Availability of Funds Announced in the HRSA Preview—Primary Health Care Programs: Community and Migrant Health Centers

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Amendment to a Notice of Availability of Funds announced in the HRSA Preview—Primary Health Care Programs: Community and Migrant Health Centers HRSA–04–030.

SUMMARY: A Notice of Availability of Funds announced in the HRSA Preview, Primary Health Care Programs: Community and Migrant Health Centers HRSA–04–030, was published in the **Federal Register** on September 4, 2003, (Volume 68, Number 171), FR Doc. 03–22427. On page 52650, under eligibility, the following service areas are added to the list of areas HRSA intends to continue to support health services, given the unmet need inherent in their provisions of services to medically underserved populations. There are no other changes.

COMMUNITY/MIGRANT HEALTH CENTERS

City	State	Expiration date
Contact: Jack Egan 301–594–4339		
Hartford	CT	1/31/2004
Great Barrington	MA	1/31/2004
Salem	MA	3/31/2004
Littleton	NH	6/30/2004
Middletown	CT	6/30/2004
White Plains	NY	11/30/2003
Penn Yan	NY	12/31/2003
Hatillo	PR	1/31/2004
Bronx	NY	1/31/2004
Morovis	PR	1/31/2004
New York	NY	6/30/2004
Baltimore	MD	11/30/2003
Contact: Jerri Regan 301–594–4283		
Tylertown	MS (2)	11/30/2003
Miami	FL	1/31/2004
Pompano Beach	FL	1/31/2004
Columbia	SC	1/31/2004
Manning	SC	1/31/2004
Foley	AL	2/29/2004
Greensboro	GA	2/29/2004
Bowling Green	KY	2/29/2004
Russellville	AL	6/30/2004
Wilmington	NC	6/30/2004
Tallahassee	FL	6/30/2004
Contact: Barbara Bailey 301–594–4317		
Houghton Lake	MI	12/31/2003
Milwaukee	WI	1/31/2004
Muncie	IN	2/29/2004
Oak Park	IL	5/31/2004
Indianapolis	IN	6/30/2004
Contact: Theresa Watkins-Bryant 301–594–4423		
Natchitoches	LA	1/31/2004
River Ridge	LA	2/29/2004
Baton Rouge	LA	5/31/2004
Opelousas	LA	6/30/2004
Contact: Jerri Regan 301–594–4283		
St. Louis	MO	1/31/2004
Columbia	MO	6/30/2004
Contact: Theresa Watkins-Bryant 301–594–4423		
Green Valley	AZ	1/31/2004
Los Angeles	CA	1/31/2004
Larkspur	CA	2/29/2004
Contact: Barbara Bailey 301–594–4317		
Klamath Falls	OR	12/31/2003

HEALTH CARE FOR THE HOMELESS

City	State	Expiration date
Contact: Jack Egan 301–594–4339		
White Plains	NY	11/30/2003
Contact: Jerri Regan 301–594–4283		
Pompano Beach	FL	1/31/2004
Contact: Theresa Watkins-Bryant 301–594–4423		
Honolulu	HI	10/31/2003
Ventura	CA	10/31/2003

SCHOOL-BASED HEALTH CENTERS

City	State	Expiration date
Contact: Jack Egan 301–594–4339		
Middletown	CT	6/30/2004
Boston	MA	8/31/2004
New York	NY	6/30/2004