

Estimated Total Annual Burden Hours: 3,187,804.80.

*Additional Information:* Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov).

*OMB Comment:* OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office

of Management and Budget, Paperwork Reduction Project, Fax: 202-395-7285, E-mail:

[OIRA\\_SUBMISSION@OMB.EOP.GOV](mailto:OIRA_SUBMISSION@OMB.EOP.GOV), Attn: Desk Officer for the Administration for Children and Families.

**Robert Sargis,**  
*Reports Clearance Officer.*  
[FR Doc. 2011-9423 Filed 4-18-11; 8:45 am]  
**BILLING CODE 4184-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Proposed Information Collection Activity; Comment Request**

*Title:* University Centers for Excellence in Developmental

Disabilities Education, Research, and Service—Annual Report.

*OMB No.:* 0970-0289.

*Description:* Section 104 (42 U.S.C. 15004) of the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (DD Act of 2000) directs the Secretary of Health and Human Services to develop and implement a system of program accountability to monitor the grantees funded under the DD Act of 2000. The program accountability system shall include the National Network of University Centers for Excellence in Developmental Disabilities Education, Research, and Service (UCEDDs) authorized under Part D of the DD Act of 2000. In addition to the accountability system, Section 154(e) (42 U.S.C. 15064) of the DD Act of 2000 includes requirements for a UCEDD Annual Report.

*Respondents:* University Centers.

**ANNUAL BURDEN ESTIMATES**

| Instrument                         | Number of respondents | Number of responses per respondent | Average burden hours per response | Total burden hours |
|------------------------------------|-----------------------|------------------------------------|-----------------------------------|--------------------|
| UCEDD Annual Report Template ..... | 67                    | 1                                  | 500                               | 33,500             |

*Estimated Total Annual Burden Hours:* 33,500.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov). All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use

of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

**Robert Sargis,**  
*Reports Clearance Officer.*  
[FR Doc. 2011-9393 Filed 4-18-11; 8:45 am]  
**BILLING CODE 4184-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2010-N-0407]

**Ivyl W. Wells: 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 FD&C Act) permanently debarring Ivyl W. Wells, MD 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 Dr. Wells was convicted of multiple felonies under Federal law for conduct relating to the regulation of a

drug product under the FD&C Act. Dr. Wells was given notice of the proposed permanent debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Dr. Wells failed to respond. Dr. Wells' failure to respond constitutes a waiver of his right to a hearing concerning this action.

**DATES:** This order is effective April 19, 2011.

**ADDRESSES:** Submit applications for special 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:** Kenny Shade, Office of Regulatory Affairs (HFC-230), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-4640.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

Section 306(a)(2)(B) of the FD&C Act (21 U.S.C. 335a(a)(2)(B)) requires debarment of an individual if FDA finds that the individual has been convicted of a felony under Federal law for conduct otherwise relating to the regulation of any drug product under the FD&C Act.

On July 12, 2006, Dr. Wells pleaded guilty to, among other things, mail fraud

in violation of 18 U.S.C. 1341 and 1346, adulterating a drug while held for sale, in violation of 21 U.S.C. 331(k) and 333(a)(2), and misbranding a drug while held for sale, in violation of 21 U.S.C. 331(k) and 333(a)(2). On December 11, 2006, the U.S. District Court for the District of Idaho entered judgment against him.

FDA's finding that debarment is appropriate is based on the felony convictions referenced herein for conduct relating to the regulation of a drug product. The factual basis for those convictions is as follows: Dr. Wells was a physician licensed by the Idaho State Board of Medicine and he owned and operated the Skinovative Laser Center. Between late 2003 and early 2004, Dr. Wells attended training sponsored by TRI-toxin International (TRI), an Arizona corporation. During the TRI seminar he learned that the TRI Botulinum Toxin Type A (TRI-toxin) was not approved for use in humans. Beginning in February 2004, Wells began ordering TRI-toxin for use in treatments in human patients at his office. The TRI-toxin came with invoices and labels on the vials of toxin that stated the product was "for research purposes only, not for human use." Dr. Wells mixed the TRI-toxin with BOTOX/BOTOX Cosmetic, causing the drug to become adulterated in violation of 21 U.S.C. 331(k) and 333(a)(2), and then he injected the mixture into patients, representing the injection as BOTOX/BOTOX Cosmetic.

From February through November 2004, Dr. Wells defrauded approximately 200 patients who received injection treatments intended to reduce wrinkles. Dr. Wells defrauded patients by representing and selling the Botulinum toxin mixture as BOTOX/BOTOX Cosmetic. Patients injected with the Botulinum toxin mixture received pre-treatment consultations during which they were informed that they were receiving BOTOX/BOTOX Cosmetic and during which they were never informed that they would be injected with a Botulinum toxin mixture not approved for use in humans. Patients injected also signed a consent form entitled "Botox Consent form" and were told by Skinovative employees that they were receiving BOTOX/BOTOX Cosmetic. Patients who received the Botulinum toxin mixture were charged prices for treatments that were the same as, or similar to, patients who had received BOTOX/BOTOX Cosmetic. Dr. Wells misrepresentation of the Botulinum toxin mixture as BOTOX/BOTOX Cosmetic resulted in the drug being misbranded in violation of 21 U.S.C. 331(k) and 333(a)(2).

As a result of his convictions, on November 22, 2010, FDA sent Dr. Wells a notice by certified mail 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 was based on a finding, under section 306(a)(2)(B) of the FD&C Act, that Dr. Wells was convicted of felonies under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. The proposal also offered Dr. Wells 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. Dr. Wells 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 Director, Office of Enforcement, Office of Regulatory Affairs, under section 306(a)(2)(B) of the FD&C Act, under authority delegated to him (Staff Manual Guide 1410.35), finds that Ivyl W. Wells 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 finding, Dr. Wells 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 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**), (see section 306(c)(1)(B), (c)(2)(A)(ii), (c)(2)(B), and section 201(dd) of the FD&C Act (21 U.S.C. 321(dd))). Any person with an approved or pending drug product application who knowingly employs or retains as a consultant or contractor, or otherwise uses the services of Dr. Wells in any capacity during Dr. Well's debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Dr. Wells provides services in any capacity to a person with an approved or pending drug product application during his period of debarment he will be subject to civil money penalties (section 307(a)(7) of the FD&C Act). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Dr. Wells during his period of debarment (section 306(c)(1)(B) of the FD&C Act).

Any application by Dr. Wells for special termination of debarment under section 306(d)(4) of the FD&C Act should be identified with Docket No. FDA-2010-N-0407 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: March 28, 2011.

**Howard Sklamberg,**

*Director, Office of Enforcement, Office of Regulatory Affairs.*

[FR Doc. 2011-9431 Filed 4-18-11; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

[Internal Agency Docket No. FEMA-3318-EM; Docket ID FEMA-2011-0001]

### North Dakota; Amendment No. 1 to Notice of an Emergency Declaration

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Notice.

**SUMMARY:** This notice amends the notice of an emergency declaration for the State of North Dakota (FEMA-3318-EM), dated April 7, 2011, and related determinations.

**DATES:** *Effective Date:* April 13, 2011.

**FOR FURTHER INFORMATION CONTACT:** Peggy Miller, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646-3886.

**SUPPLEMENTARY INFORMATION:** The notice of an emergency declaration for the State of North Dakota is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared an emergency by the President in his declaration of April 7, 2011.

Grand Forks, Pembina, Walsh, and Ward Counties for emergency protective measures (Category B), limited to direct Federal assistance, under the Public Assistance program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034,