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,

Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2011–9427 Filed 4–18–11; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

Agency Information Collection Activities: Form I–363; Extension of an Existing Information Collection; Comment Request

ACTION: 60-Day Notice of Information Collection Under Review: Form I–363, Request to Enforce Affidavit of Financial Support and Intent To Petition for Custody for Public Law 97–359 Amerasian; OMB Control No. 1615–0022.

The Department of Homeland Security, U.S. Citizenship and Immigration Services (USCIS) will be submitting the following information collection request for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection is published to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted for 60 days until June 20, 2011.

During this 60-day period, USCIS will be evaluating whether to revise the Form I–363. Should USCIS decide to revise Form I–363 we will advise the public when we publish the 30-day notice in the **Federal Register** in accordance with the Paperwork Reduction Act. The public will then have 30 days to comment on any revisions to the Form I–363.

Written comments and suggestions regarding items contained in this notice, and especially with regard to the estimated public burden and associated response time should be directed to the Department of Homeland Security (DHS), USCIS, Chief, Regulatory Products Division, Office of the Executive Secretariat, Clearance Officer, 20 Massachusetts Avenue, NW., Washington, DC 20529–2020. Comments may also be submitted to DHS via facsimile to 202–272–0997 or via e-mail at *rfs.regs@dhs.gov.* When submitting comments by e-mail please add the OMB Control Number 1615–0022 in the subject box.

Note: The address listed in this notice should only be used to submit comments concerning this information collection. Please do not submit requests for individual case status inquiries to this address. If you are seeking information about the status of your individual case, please check "My Case Status" online at: *https://egov.uscis.gov/cris/Dashboard.do,* or call the USCIS National Customer Service Center at 1–800–375–5283.

Written comments and suggestions from the public and affected agencies concerning the collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension of an existing information collection.

(2) *Title of the Form/Collection:* Request to Enforce Affidavit of Financial Support and Intent to Petition for Custody for Public Law 97–359 Amerasian.

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* Form I–363, U.S. Citizenship and Immigration Services (USCIS).

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or households. Form I–363 is used by applicants to ensure the financial support of a U.S. citizen. Without the use of Form I–363, the USCIS is not able to ensure the child does not become a public charge.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 50 responses at 30 minutes (0.50 hours) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 25 annual burden hours.

If you need a copy of the information collection instrument, please visit the Web site at: *http://www.regulations.gov/.*

We may also be contacted at: USCIS, Regulatory Products Division, Office of the Executive Secretariat, 20 Massachusetts Avenue, NW., Room 5012, Washington, DC 20529–2020, Telephone number 202–272–8377.

Dated: April 14, 2011.

Sunday A. Aigbe,

Chief, Regulatory Products Division, Office of the Executive Secretariat, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2011–9437 Filed 4–18–11; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

Agency Information Collection Activities: Form I–765, Extension of an Existing Information Collection; Comment Request

ACTION: 60-Day Notice of Information Collection Under Review: Form I–765, Application for Employment Authorization; OMB Control No. 1615–0040.

The Department of Homeland Security, U.S. Citizenship and Immigration Services (USCIS) will be submitting the following information collection request for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection is published to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted for sixty days until June 20, 2011.

During this 60 day period, USCIS will be evaluating whether to revise the Form I–765. Should USCIS decide to revise Form I–765 we will advise the public when we publish the 30-day notice in the **Federal Register** in accordance with the Paperwork Reduction Act. The public will then have 30 days to comment on any revisions to the Form I–765.