TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Portion of study	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
Screener	10,000	1	10,000	0.0055	55
Pretest	150	1	150	0.42	63
Experiment	5,000	1	5,000	0.25	1,250
Total					1,368

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: February 25, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–4740 Filed 3–2–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0344]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Testing Communications on Medical Devices and Radiation-Emitting Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Testing Communications on Medical Devices and Radiation-Emitting Products" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 18, 2010 (75 FR 63838), the Agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0678. The approval expires on January 31, 2014. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: February 16, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–4738 Filed 3–2–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2006–N–0238] (formerly 2006N–0062)

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Expanded Access to Investigational Drugs for Treatment Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Expanded Access to Investigational Drugs for Treatment Use" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3792, *Elizabeth.Berbakos@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 14, 2006 (71 FR 75147), the Agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0653. The approval expires on December 31, 2011. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: February 23, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–4739 Filed 3–2–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0478]

Albert Poet: 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 Albert Poet, MD from providing services in any capacity to a person that has an approved or pending drug product application. We base this order on a finding that Dr. Poet was convicted of felonies under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. Dr. Poet was given notice of the proposed permanent debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Dr. Poet failed to respond. Dr. Poet's failure to respond constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is effective March 3, 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, Division of Compliance Policy (HFC–230), Office of Enforcement, Office of Regulatory

Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240–632–6844.

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 September 28, 2007, the U.S. District Court District of New Jersey entered judgment against Dr. Poet for 13 counts of mail fraud in violation of 18 U.S.C. 2 and 1341 and 1 count of causing a drug to be misbranded while it was held for sale after shipment in interstate commerce with the intent to defraud or mislead in violation of 21 U.S.C. 331(k), 333(a)(2), and 352(i)(3).

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: During 2003–2004, Dr. Poet was a physician licensed to practice medicine in the State of New Jersey. Dr. Poet owned and operated the Shore Laser Center and PEAU, both located in New Jersey. As part of his practice, Dr. Poet injected patients with BOTOX, a Botulinum Toxin Type A drug.

From on or about December 4, 2003, through in or about December 2004, Dr. Poet knowingly and willfully devised a scheme and artifice to defraud and to obtain money and property by means of false and fraudulent pretenses, representations, and promises. He maintained a Web site and placed regular advertisements in local newspapers offering BOTOX treatments at his office. Between December 4, 2003, and November 8, 2004, Dr. Poet placed 13 orders for a total of 26 vials of TRI–Toxin, a Botulinum Toxin Type A drug manufactured by Toxin Research International, Inc. TRI–Toxin was labeled "For Research Purposes Only, Not for Human Use." Dr. Poet injected many of the approximately 130 patients who sought BOTOX treatments with unapproved TRI–Toxin between January 1, 2004, and December 1, 2004. As part of his scheme to defraud, Dr. Poet did not inform most of his patients receiving the TRI–Toxin injections that they were receiving injections of a product not approved by FDA. Dr. Poet charged patients the same price for the cheaper, unapproved TRI–Toxin and the approved BOTOX. For purposes of executing the scheme and artifice, Dr. Poet knowingly and willfully caused the TRI–Toxin to be delivered by private and commercial interstate carrier.

As a result of his convictions, on December 13, 2010, FDA sent Dr. Poet 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. Poet 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. Poet 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. Poet 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 the Director (Staff Manual Guide 1410.35), finds that Albert Poet 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. Poet 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) (see **DATES**) (see sections 306(c)(1)(B) and (c)(2)(A)(ii), and 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. Poet, in any capacity during Dr. Poet'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. Poet 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. Poet during his period of debarment (section 306(c)(1)(B) of the FD&C Act).

Any application by Dr. Poet for special termination of debarment under section 306(d)(4) of the FD&C Act should be identified with Docket No. FDA–2010–N–0478 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: February 16, 2011.

Howard Sklamberg,

Director, Office of Enforcement, Office of Regulatory Affairs.

[FR Doc. 2011–4778 Filed 3–2–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–1981–N–0077 (formerly 81N–0393), FDA–1981–N–0248 (formerly 81N–0396), FDA–1982–N–0046 (formerly 82N–0095), FDA–1982–N–0264 (formerly 82N–0096), and FDA–1983–N–0137 (formerly 83N–0095); DESI 6514, 11935, and 12152]

Drugs for Human Use; Drug Efficacy Study Implementation; Oral Prescription Drugs Offered for Relief of Symptoms of Cough, Cold, or Allergy; Withdrawal of Hearing Requests; Final Resolution of Dockets

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that all outstanding hearing requests pertaining to oral prescription drugs offered for relief of symptoms of cough, cold, or allergy, Docket Nos. FDA–1981–N–0077 (formerly 81N–0393), FDA–1981–N–0248 (formerly 81N–0396), FDA–1982–N–0046 (formerly 82N–0095), FDA–1982–N–0264 (formerly 82N–0096), and FDA–1983–N–0137 (formerly 83N–0095), have been withdrawn. Therefore, shipment in interstate commerce of the products identified in those dockets, or any identical, related, or similar (IRS) product that is not the subject of an approved new drug application (NDA) or abbreviated new drug application (ANDA) (other than an over-the-counter (OTC) product that complies with an