Washington, DC 20503. Attn: Desk Officer for ACF.

Dated: January 7, 2003.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 03–639 Filed 1–10–03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0566]

Renee Peugeot; 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 Renee Peugeot 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 Ms. Peugeot was convicted of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of a drug product. Ms. Peugeot failed to request a hearing and, therefore, has waived her opportunity for a hearing concerning this action.

DATES: This order is effective January 13, 2003.

ADDRESSES: Submit applications for termination of debarment to the Dockets Management Branch (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 August 31, 2000, the U.S. District Court for the Northern District of Alabama entered judgment against Ms. Peugeot for two counts of making false statements to an agency of the United States, two counts of mail fraud, and one count of conspiracy to commit offenses against the United States, Federal felony offenses under 18 U.S.C. 2, 1001, 1341, and 371, respectively. These offenses were committed as part of the development of a new drug for which Ms. Peugeot was conducting efficacy trials.

As a result of this conviction, FDA served Ms. Peugeot by certified mail on May 8, 2002, a notice proposing to permanently debar Ms. Peugeot from providing services in any capacity to a person that has an approved or pending drug product application. The proposal also offered Ms. Peugeot an opportunity for a hearing on the proposal. The proposal was based on a finding, under section 306(a)(2)(A) of the act (21 U.S.C. 335a(a)(2)(A)), that Ms. Peugeot was convicted of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of a drug product. Ms. Peugeot was provided 30 days to file objections and request a hearing. Ms. Peugeot did not request a hearing. Her failure to request a hearing constitutes a waiver of her opportunity for a hearing and a waiver of any contentions concerning her debarment.

II. Findings and Order

Therefore, the Director, Center for Drug Evaluation and Research, under section 306(a)(2)(A) of the act, and under authority delegated to her (21 CFR 5.34), finds that Ms. Renee Peugeot has been convicted of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of a drug product.

As a result of the foregoing finding, Ms. Renee Peugeot 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 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 Ms. Peugeot, in any capacity, during her 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 Ms. Peugeot, during her period of debarment, provides services in any capacity to a person with an approved or pending drug product application, she 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 Ms. Peugeot during her period of debarment.

Any application by Ms. Peugeot for termination of debarment under section 306(d)(4) of the act should be identified with Docket No. 01N–0566 and sent to the Dockets Management Branch (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: December 23, 2002.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 03–663 Filed 1–10–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0565]

Harry W. Snyder, Jr.; 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 Harry W. Snyder, Jr., 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. Snyder was convicted of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of a drug product. Mr. Snyder failed to request a hearing and, therefore, has waived his opportunity for a hearing concerning this action.

DATES: This order is effective January 13, 2003.

ADDRESSES: Submit applications for termination of debarment to the Dockets Management Branch (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 August 31, 2000, the U.S. District Court for the Northern District of Alabama entered judgment against Mr. Snyder for two counts of making false statements to an agency of the United States, two counts of mail fraud, and one count of conspiracy to commit

offenses against the United States, Federal felony offenses under 18 U.S.C. 2, 1001, 1341, and 371, respectively. These offenses were committed as part of the development of a new drug for which Mr. Snyder was conducting efficacy trials.

As a result of this conviction, FDA served Mr. Snyder by certified mail on May 8, 2002, a notice proposing to permanently debar Mr. Snyder from providing services in any capacity to a person that has an approved or pending drug product application. The proposal also offered Mr. Snyder an opportunity for a hearing on the proposal. The proposal was based on a finding, under section 306(a)(2)(A) of the act (21 U.S.C. 335a(a)(2)(A)), that Mr. Snyder was convicted of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of a drug product. Mr. Snyder was provided 30 days to file objections and request a hearing. Mr. Snyder 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)(A) of the act, and under authority delegated to her (21 CFR 5.34), finds that Mr. Harry W. Snyder, Jr., has been convicted of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of a drug product.

As a result of the foregoing finding, Mr. Harry W. Snyder, Jr., 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 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. Snyder, 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. Snyder, 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. Snyder during his period of debarment.

Any application by Mr. Snyder for termination of debarment under section 306(d)(4) of the act should be identified with Docket No. 01N–0565 and sent to the Dockets Management Branch (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: December 23, 2002.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 02M–0298, 02M–0299, 02M–0295, 02M–0381, 02M–0310, 02M–0348, 02M–0335, 02M–0353, 02M–0352, 02M–0336, 02M–0322, 02M–0361, 02M–0412, 02M–0409]

Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and the agency's Dockets Management Branch.

ADDRESSES: Submit written requests for copies of summaries of safety and effectiveness to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please cite the appropriate docket number as listed in table 1 of this document when submitting a written request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries of safety and effectiveness.

FOR FURTHER INFORMATION CONTACT: Thinh Nguyen, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2186.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 30, 1998 (63 FR 4571), FDA published a final rule that revised 21 CFR 814.44(d) and 814.45(d) to discontinue individual publication of PMA approvals and denials in the **Federal Register**, providing instead to post this information on the Internet on FDA's home page at http://www.fda.gov. In addition, the regulations provide that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were announced during that quarter. FDA believes that this procedure expedites public notification of these actions because announcements can be placed on the Internet more quickly than they can be published in the **Federal Register**, and FDA believes that the Internet is accessible to more people than the **Federal Register**.

In accordance with section 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the act. The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The following is a list of approved PMAs for which summaries of safety and effectiveness were placed on the Internet from July 1, 2002, through September 30, 2002. There were no denial actions during this period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.