

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N-0566]

DMB
Display Date 1-10-03
Publication Date 1-11-03
Certifier R. LEDESMA

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 [insert date of publication in the FEDERAL REGISTER].

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.

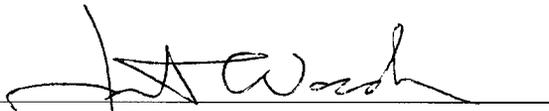
As a result of the foregoing finding, Ms. Renee Peugeot is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under section 505, 512, or 802 of the act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service 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.

DEC 23

Dated: _____.



Janet Woodcock, M.D.

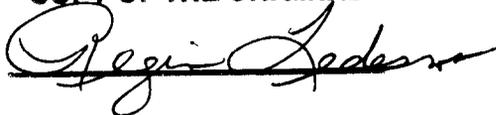
Director, Center for Drug Evaluation and Research,

js

js

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]
Billing Code 4160-01-S

**CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL**





js