through (h), 1003.21(a) through (d), 1003.22(a) and (b), 1003.30(a) and (b), 1003.31(a) and (b), 1004.2(a) through (i), 1004.3(a) through (i), 1004.4(a) through (h) and 1005.21(a) through (c). Other requirements are not included because they constitute a disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public (5 CFR 1320.3(c)(2)).

Dated: August 20, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–22857 Filed 8–27–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0221]

Benzodiazepines and Related Substances; Criteria for Scheduling Recommendations Under the Controlled Substance Act; Notice of Public Hearing Modification

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) in conjunction with other Federal agencies is announcing that the part 15 public hearing on benzodiazepines and related substances originally scheduled for September 11 and 12, 1997, will be held only on September 11, 1997. The public hearing will not continue to September 12, 1997. The decision to forego the second day is based on the limited number of respondents submitting notices of participation in the hearing.

DATES: The hearing will be held on Thursday September 11, 1997, from 9 a.m. to 4 p.m. The closing date for comments will be October 17, 1997.

ADDRESSES: The public hearing will be held at the Renaissance Hotel, 999 Ninth St. NW., Washington, DC. Comments are to be sent to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Transcripts of the public hearing may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the hearing, at a cost of 10 cents per page. The transcript of the public hearing, copies of data and information submitted during the hearing, and any written comments will be available for review at the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Nicholas P. Reuter, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, rm. 15–22, Rockville, MD 20857, 301–827–1696, FAX 301–443– 0232, e-mail ''nreuter@bangate.fda.gov''.

SUPPLEMENTARY INFORMATION:

In a notice published in the Federal Register of June 19, 1997 (62 FR 33418), FDA in conjunction with other Federal agencies announced that it would convene a part 15 public hearing on benzodiazepines and related substances. The public hearing was scheduled for Thursday, September 11, 1997 and part of Friday, September 12, 1997.

Persons who wished to participate in the hearing were asked to file a notice of participation with the Dockets Management Branch (address above) on or before August 14, 1997. In response to that notice, eight individuals representing various organizations indicated their interest in participating in the hearing. FDA, along with the other participating agencies, have determined that the number of individuals indicating an interest in participating in the hearing can be accommodated in one full day and that there is no need to continue the hearing to the second day. Therefore, the public hearing will be held at the address above from approximately 9 a.m. until 4 p.m. on September 11, 1997.

Interested parties may still sign up to participate in the hearing. The June 19, 1997, notice included a provision whereby persons may give oral notice of participation by calling Nicholas Reuter (telephone number above) no later than August 29, 1997. This notice extends until September 3, 1997, the opportunity to give oral notice of participation. Those persons who give oral notice of participation should also submit written notice containing the information described above to the Dockets Management Branch by the close of business September 8, 1997.

Dated: August 22, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–22935 Filed 8–25–97; 11:56 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96N–0256]

Norma D. Banks; 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 Norma D. Banks, 3688 West Minarets Ave., Fresno, CA 91331, 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. Banks was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the act. Ms. Banks has failed to request a hearing and, therefore, has waived her opportunity for a hearing concerning this action.

EFFECTIVE DATE: August 28, 1997.

ADDRESSES: Application for termination of debarment to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Leanne Cusumano, 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

Ms. Banks was employed by H. R. Cenci Laboratories, Inc. (Cenci), as Director of Quality Assurance and Regulatory Affairs. In that capacity, on November 17, 1993, she knowingly and willfully made false, fictitious, and fraudulent representations in a matter within the jurisdiction of FDA. Specifically, she misrepresented to FDA's Office of Generic Drugs information contained in an annual report that stability tests for three drug products manufactured by H. R. Cenci Laboratories, Inc. (i.e., promethazine syrup with phenylephrine, promethazine syrup with codeine, and promethazine syrup with phenylephrine and codeine), were uniformly passing, when, in fact, several stability test results were failing.

On January 25, 1996, the United States District Court for the District of Maryland entered judgment against Ms.

Banks for one count of knowingly and willfully making false, fictitious, and fraudulent statements and representations to a Federal agency as to material facts, a Federal felony under 18 U.S.C. 1001.

As a result of this conviction, FDA served Ms. Banks by certified mail on September 26, 1996, a notice proposing to permanently debar her from providing services in any capacity to a person that has an approved or pending drug product application, and offered her an opportunity for a hearing on the proposal. The proposal was based on a finding, under section 306(a)(2)(B) of the act (21 U.S.C. 335a(a)(2)(B)), that Ms. Banks was convicted of a felony under Federal law for conduct relating to the regulation of a drug product. Ms. Banks 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) of the act, and under authority delegated to her (21 CFR 5.99(b)), finds that Ms. Norma D. Banks has been convicted of a felony under Federal law for conduct relating to the regulation of a drug product.

As a result of the foregoing finding, Ms. Norma D. Banks is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under section 505, 507, 512, or 802 of the act (21 U.S.C. 355, 357, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective August 28, 1997 (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. Banks 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. Banks, 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 or abbreviated antibiotic drug applications submitted by or with the assistance of Ms. Banks during her period of debarment.

Any application by Ms. Banks for termination of debarment under section 306(d)(4) of the act should be identified with Docket No. 96N–0256 and sent to the Dockets Management Branch (address above). 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: August 12, 1997.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 97–22856 Filed 8–27–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0298]

Distributor Medical Device Reporting; Draft Compliance Policy Guide; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft Compliance Policy Guide (CPG) entitled ''Distributor Medical Device Reporting.'' The purpose of the CPG is to provide guidance concerning the interpretation and applicability of some of the provisions in the Medical Device Distributor Reporting Regulation. FDA believes that the following guidance will improve the administration and efficiency of medical device distributor reporting as well as the quality of information received.

DATES: Written comments on the draft CPG may be submitted by November 26, 1997.

ADDRESSES: Submit written requests for single copies of the draft CPG to the Division of Small Manufacturers Assistance (DSMA), Center for Devices and Radiological Health (CDRH) (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–443–6597 or outside MD 1–800–638–2041. Send two self-addressed adhesive labels to assist that office in processing your requests, or FAX your request to 301–443–8818. Facsimiles of the draft CPG are available from DSMA. To receive the draft CPG on your fax machine, call the CDRH Facts-On-Demand system at 1–800–899–0381 or 301–827–0111 from a touch tone telephone. At the first voice prompt press ''1'' to access DSMA Facts, at the second voice prompt press ''2'' and then enter the document number, ''120'' followed by the pound sign, ''#''. Follow the remaining voice prompts to complete the request. Submit written comments on the draft CPG to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Chester T. Reynolds, Office of Compliance (HFZ–300), Center for Devices and Radiological Health, Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–4618, ext. 114.

SUPPLEMENTARY INFORMATION:

I. Background

Distributors of devices have been required, by statute, to report device related deaths, serious illnesses, serious injuries and malfunctions to FDA and the manufacturers of the devices since May 28, 1992. The regulations that implemented the statutory provisions can be found in parts 804 and 807 (21 CFR parts 804 and 807).

Since 1993, FDA has received thousands of Medical Device Reports (MDR's) submitted in response to part 804. As a result of this experience, FDA has developed a draft CPG to provide guidance concerning the interpretation and applicability of some of the provisions of the Distributor Medical Device Reporting Regulation. For practical purposes, FDA intends to interpret the reporting standards for both domestic distributors and importers to be the same. In exercising its enforcement discretion, the agency does not plan to initiate regulatory action involving distributor requirements for staff training and education. Additionally, FDA encourages distributors to voluntarily use the reporting form MEDWATCH FDA Form 3500A. The agency believes that using this form will reduce the paperwork and level of effort for distributors, manufacturers, and FDA. This draft guidance document represents the agency's current thinking on distributor medical device reporting. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

II. Request for Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft