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]

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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.