TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN—Continued

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
203.37(d)	2,208	1	2,208	.08	177
203.38(a)	2,208	1	2,208	3.00	6,624
203.39(g)	3,221	1	3,221	2.00	6,442
203.50(a)	125	100	12,500	.08	1,000
Total					2,300,628

TABLE 3.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
203.23(a) and (b)	31,676	5	158,380	.25	39,595
203.23(c)	31,676	5	158,380	.08	12,670
203.30(a)(2) and 203.31(a)(2)	2,208	100	220,800	.50	110,400
203.31(d)(1) and (d)(2)	2,208	1	2,208	40.00	88,320
203.31(d)(4)	442	1	442	24.00	10,608
203.31(e)	2,208	1	2,208	1.00	2,208
203.34	2,208	1	2,208	40.00	88,320
203.37(a)	25	1	25	18.00	450
203.37(b)	200	1	200	18.00	3,600
203.38(b)	2,208	14,543	32,111,457	.02	642,229
203.39(d)	65	1	65	1.00	65
203.39(e)	3,221	1	3,221	.50	1,610
203.39(f)	3,221	1	3,221	8.00	25,768
203.39(g)	3,221	1	3,221	8.00	25,768
203.50(a)	125	100	12,500	.17	2,125
203.50(b)	125	100	12,500	.50	6,250
203.50(d)	691	1	691	2.00	1,382
Total					1,061,368

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

Dated: November 21, 2002.

Margaret M. Dotzel,

Assistant Commissioner for Policy.

[FR Doc. 02–30404 Filed 11–29–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1527]

Laverne M. Charpentier; Denial of Hearing; Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is denying Ms. Laverne M. Charpentier's request for a hearing and is issuing an order under the Federal Food, Drug, and Cosmetic Act (the act) debarring Ms. Laverne M. Charpentier for 5 years 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. Charpentier was convicted of a felony under Federal law for conspiring to make false statements in matters within the jurisdiction of a Government agency, and that Ms. Charpentier's conduct undermined the process for the regulation of drugs. Ms. Charpentier has failed to file with the agency information and analyses sufficient to create a basis for a hearing concerning this action.

DATES: This order is effective December 2, 2002.

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: Mary Catchings, 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 October 21, 1997, the U.S. District Court for the Central District of California accepted the plea of Ms. Laverne M. Charpentier to one count of conspiring to make false statements in matters within the jurisdiction of a Government agency under 18 U.S.C. 371 and 1001.

Ms. Charpentier, a former drug study coordinator, was employed by a private company retained by drug manufacturers to conduct clinical studies of new pharmaceutical products to be submitted to FDA in support of approval of the drug products. In her capacity as a drug study coordinator, Ms. Charpentier participated in the conduct of clinical studies to test the safety and effectiveness of investigational new drugs. Ms. Charpentier admitted that she, among other things: (1) Falsely reported that certain subjects participated in clinical trials when in fact, they had not; (2) substituted samples and data from qualifying subjects for nonqualifying subjects; and (3) enrolled nonexistent and nonqualifying subjects in the clinical studies and falsified data for those nonexistent and nonqualifying subjects.

As a result of Ms. Charpentier's conviction, FDA served her by certified letter on May 14, 2002, a proposal to debar her for 5 years from providing services in any capacity to a person that has an approved or pending drug product application. The proposal also offered Ms. Charpentier an opportunity for a hearing on the proposal. FDA based the debarment proposal on a

finding, under section 306(b)(2)(B)(i)(II) and (a)(2) of the act (21 U.S.C. 335a(b)(2)(B)(i)(II) and (a)(2)) that Ms. Charpentier was convicted of a felony under Federal law for conspiring to make false statements in matters within the jurisdiction of a Government agency, FDA, and that Ms. Charpentier's conduct undermined the process for the regulation of drugs.

The certified letter also informed Ms. Charpentier that her request for a hearing could not rest upon mere allegations or denials, but must present specific facts showing that there was a genuine and substantial issue of fact requiring a hearing. The letter also informed Ms. Charpentier that if it conclusively appeared from the face of the information and factual analyses in her request for a hearing that there was no genuine and substantial issue of fact that precluded the order of debarment, FDA would enter summary judgment against her and deny her request for a hearing.

In a letter dated May 28, 2002, Ms. Charpentier requested a hearing on the proposal and indicated she would submit further information to justify a hearing. Ms. Charpentier filed a letter dated July 1, 2002, in which she again requested an opportunity for a hearing. In her request for a hearing, Ms. Charpentier discusses her motives for her illegal conduct, her embarrassment and her financial problems resulting from her conviction. Such matters do not create a basis for a hearing because hearings will not be granted on mere allegations, denials, or general descriptions of positions and contentions, nor on data and information insufficient to justify the factual determination urged (see 21 CFR 12.24(b)(2) and (b)(3)).

II. Denial of Hearing

In her requests for a hearing, Ms. Charpentier does not present any arguments or information to show why she should not be debarred. Ms. Charpentier acknowledges that the agency is aware of the facts and states that she submitted the July 1, 2002, request for a hearing to set forth ''some of the circumstances that led up to this unfortunate situation.'' Ms. Charpentier's explanation of the facts leading to her conviction does not raise a genuine and substantial issue of fact requiring a hearing.

Ms. Charpentier is subject to permissive debarment based on: (1) FDA's findings that she was convicted of a Federal felony that undermined the regulatory process (section 306(b)(2)(B)(i)(II) and (a)(2) of the act)) and (2) FDA's determination that debarment is appropriate in this case based on a consideration of applicable factors set forth in section 306(c)(3) of the act. After FDA finds that the statutory criteria for permissive debarment has been met, the only relevant issue is whether Ms. Charpentier was, in fact, convicted as alleged in the proposal to debar. Ms. Charpentier does not dispute that she pled guilty to one Federal felony count for actions that undermined the regulation of drug products. In fact, in her letter of July 1, 2002, Ms. Charpentier: (1) Acknowledges wrongdoing, stating that she made a ''big mistake''; (2) expresses her remorse; and (3) offers an apology for her illegal conduct. Section 306(l)(1)(B) of the act includes in its definition of a conviction, a guilty plea. The facts underlying Ms. Charpentier's conviction have been established by her conviction and, therefore, are not at issue. In her July 1, 2002, letter, Ms. Charpentier's discusses the motives resulting in her conviction, her remorse, her apology, and her statements indicating that she will not again participate in illegal activity. This information does not justify a hearing. Although such information may be considered in determining whether to grant special termination of debarment under section 306(d)(4)(C) of the act, this information does not raise a factual dispute regarding Ms. Charpentier's conviction, but rather supports it. Thus, FDA finds that Ms. Charpentier has failed to identify any genuine and substantial issue of fact requiring a hearing. Accordingly, FDA denies Ms. Charpentier's request for a hearing.

III. Findings and Order

Therefore, the Deputy Commissioner, under section 306(b) of the act and under authority delegated to him (21 CFR 5.10), finds that Ms. Laverne M. Charpentier has been convicted of a felony under Federal law for conspiracy to make false statements to a Government agency, and that Ms. Charpentier's conduct undermined the process for the regulation of drugs.

As a result of the foregoing findings, Ms. Laverne M. Charpentier is debarred for 5 years 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 act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective December 2, 2002 (sections 306 (c)(1)(B) and (c)(2)(A)(iii) 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. Charpentier, in any capacity, during her period of debarment, will be subject to civil money penalties. If Ms. Charpentier, 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. In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Ms. Charpentier during her period of debarment.

Any application by Ms. Charpentier for termination of debarment under section 306(d)(4) of the act should be identified with Docket No. 00N–1527 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: November 19, 2002.

Lester M. Crawford,

Deputy Commissioner.

[FR Doc. 02–30482 Filed 11–29–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0451]

Withdrawal of 20 Guidances on Individual Product Labeling

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of 20 individual product labeling guidances. The guidances are being withdrawn because they are out of date and of little use to the generic drug industry. The agency has developed other guidance and resources to assist the industry in obtaining up-to-date labeling for reference listed drugs.

DATES: General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See