All profiles issued as ''Drafts for Public Comment'' represent ATSDR's best efforts to provide important toxicological information on priority hazardous substances. We are seeking public comments and additional information which may be used to supplement these profiles. ATSDR remains committed to providing a public comment period for these documents as a means to best serve public health and our clients.

Dated: October 8, 1999.

Georgi Jones,

Director, Office of Policy and External Affairs, Agency for Toxic Substances and Disease Registry.

[FR Doc. 99–27025 Filed 10–14–99; 8:45 am]

BILLING CODE 4163–70–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–2674]

Jay Marcus; Proposal to Debar; Opportunity for a Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is proposing to issue an order under the Federal Food, Drug, and Cosmetic Act (the act) permanently debarring Mr. Jay Marcus from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this proposal on a finding that Mr. Marcus was convicted of a felony under Federal law for conspiracy to defraud the United States. This notice also offers Mr. Marcus an opportunity for a hearing on the proposal. The agency is issuing this notice in the **Federal Register** because all other appropriate means of service of the notice upon Mr. Marcus have proven ineffective.

DATES: Submit written requests for a hearing by November 15, 1999.

ADDRESSES: Submit written requests for a hearing and supporting information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061 Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Christine F. Rogers, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION:

I. Conduct Related to Conviction

On October 21, 1994, the United States District Court for the District of Maryland accepted Mr. Marcus' plea of guilty to one count of conspiracy to defraud the United States under 18 U.S.C. 371 and sentenced Mr. Marcus for the crime. The underlying facts supporting this felony conviction, and to which Mr. Marcus stipulated to in his plea agreement, are as follows:

Mr. Marcus was the president and chief executive officer of Halsey Drug Co., Inc. (Halsey), a generic drug manufacturer with facilities located in Brooklyn, NY. Halsey had obtained approval to market certain generic drug products. Master formulas approved in the abbreviated new drug applications (ANDA's) for those products specified the ingredients and manufacturing processes to be used. FDA regulations required Halsey to maintain accurate and contemporaneous written batch records documenting the raw materials used and the manufacturing processes followed for each batch of such generic drug products.

With Mr. Marcus' knowledge and sometimes at his direction or with his approval, Halsey employees responded to problems in the production of Halsey's products by reworking batches without approval from FDA, including on some occasions regrinding tablets and adding lubricants. To conceal these practices from FDA, Halsey employees did not document these reworks on the batch record. For some Halsey products, problems encountered in manufacturing large production batches led Halsey employees to develop alternate formulas and manufacturing processes that replaced the FDA-approved master formulas. These alternate formulas, kept on handwritten ''phony cards,'' sometimes substituted unapproved inactive ingredients. Although Halsey employees followed the phony card formulas, they created false batch records that made it appear as though Halsey had followed the FDA-approved master formulas, with the intent to conceal the phony card system from FDA.

For the product quinidine gluconate 324-milligram (mg) tablets, Halsey employees created a phony card formula to solve a problem with the dissolution rate of large-scale production batches. Quinidine gluconate is a medication that treats irregular heartbeats. The phony card formula included additions of the unapproved inactive ingredients magnesium stearate and stearic acid. Mr. Marcus became aware of the unapproved deviations in the formula and manufacturing process for quinidine gluconate. With other members of Halsey's management, Mr. Marcus discussed filing the required preapproval supplement to get FDA's approval for those changes. However, Mr. Marcus and other members of Halsey's management realized that FDA would consider the changes significant and would probably require an expensive bioequivalence study to test the performance of Halsey's alternate formula. Because filing a preapproval supplement might require an additional bioequivalence study and delay Halsey's marketing of the product for years, Mr. Marcus and the others decided to continue using the phony card system without filing a supplement. Mr. Marcus and other Halsey employees caused batch number 2F24H of quinidine gluconate 324-mg tablets to be manufactured according to the unapproved, phony card formula, introduced into interstate commerce, and delivered to Baltimore, MD on August 27, 1992.

Halsey employees used alternate formulas and created false batch records for other products, including acetaminophen and codeine phosphate tablets, propylthiouracil tablets, and metronidazole tablets. When an FDA inspection in 1989 revealed irregularities at the company, Mr. Marcus and others directed the creation of false batch records for acetaminophen and codeine phosphate tablets in an attempt to cover up the phony card system.

During the course of manufacturing research and development batches, Halsey employees created false paperwork for submission to FDA to make it appear that they had made more or larger batches than they actually made. Mr. Marcus later became aware of that conduct and participated in conduct to cover up those falsifications.

Between August 23, 1989, and October 11, 1989, FDA inspected Halsey's facilities to determine Halsey's compliance with the act. On or about August 29, 1989, Mr. Marcus directed a Halsey employee to create a falsified raw material inventory card for fenoprofen calcium. Mr. Marcus knew that the raw material card falsely stated that Halsey had received 50 kilograms of fenoprofen calcium on September 11, 1987. Mr. Marcus knew that in fact Halsey had received half that amount. The purpose of the falsification was to conceal from FDA that Halsey did not have enough raw material from that shipment to manufacture its pilot batches in the sizes represented in ANDA's for the generic drug products fenoprofen calcium 200-mg capsules, fenoprofen calcium 300-mg capsules,

and fenoprofen calcium 600-mg tablets. Mr. Marcus understood that the falsified raw material card would be provided to FDA inspectors that day, and in fact, the falsified card was produced to FDA inspectors that day.

II. FDA's Finding

Section 306(b)(2)(B)(i) of the act (21 U.S.C. 335a(b)(2)(B)(i)) permits FDA to debar an individual if it finds that the individual has been convicted of a felony under Federal law for conspiracy to commit a criminal offense related to the development or approval, including the process for the development or approval, of any drug product, or otherwise related to the regulation of drug products, and that the offense undermined the process for the regulation of drugs. Mr. Marcus' felony conviction under 18 U.S.C. 371 for conspiracy to defraud the United States, specifically for conspiracy to submit false ANDA information to FDA, is a conviction related to the development or approval of drug products. Submission of false information to an ANDA undermines the process for the regulation of drugs. Accordingly, the agency finds that Mr. Marcus is eligible for permissive debarment under section 306(b)(2)(B)(i) of the act.

Under section 306(l)(2) of the act, permissive debarment may be applied when an individual acted or was convicted within the 5 years preceding initiation of an agency action proposed to be taken under section 306(b)(2)(B) of the act. Under section 306(c)(2)(A)(iii) of the act, the agency may debar Mr. Marcus for up to 5 years for each offense. FDA finds that Mr. Marcus is eligible to be debarred for 5 years under section 306(b)(2)(B)(i) of the act because he was convicted of one count of conspiracy to commit a crime relating to the development or approval of drug products.

Section 306(c)(3) of the act provides several considerations for determining the appropriateness and the period of permissive debarment. The considerations applicable to a decision to debar an individual include: (1) Nature and seriousness of the offense involved, (2) nature and extent of management participation in any offense, (3) nature and extent of voluntary steps to mitigate the impact on the public, and (4) prior convictions involving matters within the jurisdiction of the FDA. These considerations are discussed below.

A. Nature and Seriousness of the Offense Involved

Mr. Marcus was convicted of one count of conspiracy to defraud the United States for knowingly permitting, and sometimes directing, employees of Halsey to manufacture prescription drugs according to formulas that deviated from FDA-approved formulas. Mr. Marcus committed violations with regard to three drugs: Quinidine gluconate tablets, acetaminophen and codeine tablets, and fenoprofen calcium tablets. Quinidine gluconate is used to treat irregular heartbeats; acetaminophen and codeine are used to treat mild to moderately severe pain; fenoprofen calcium is used for the treatment of arthritis.

The agency finds that Mr. Marcus' conduct: (1) Created a risk of injury to consumers; (2) potentially undermined the safety, effectiveness, and quality of several drugs; and (3) otherwise undermined the integrity of the drug approval and regulatory processes. Mr. Marcus' conduct created a risk of injury to consumers by marketing adulterated drugs. Mr. Marcus' conduct potentially undermined the safety, effectiveness, and quality of several drugs by changing master formulas and adding unapproved ingredients. Mr. Marcus' conduct undermined the integrity of the drug approval and regulatory process by leading FDA investigators to evaluate drugs different from those marketed by Halsey and by providing to consumers drugs that had not been approved by the FDA for distribution. Accordingly, the agency considers the conduct underlying Mr. Marcus' conviction an extremely unfavorable factor because Mr. Marcus' actions potentially undermined the safety and effectiveness of drugs used for life-threatening or serious conditions.

B. Nature and Extent of Management Participation in Any Offense

Mr. Marcus was the president and chief executive officer of Halsey. Mr. Marcus directed Halsey employees to prepare false batch records. Among other acts, Mr. Marcus caused a batch of quinidine gluconate 324-mg tablets to be manufactured according to an unapproved formula and to be introduced into interstate commerce. Therefore, the agency considers the nature and extent of Mr. Marcus' participation an unfavorable factor.

C. Nature and Extent of Voluntary Steps to Mitigate the Impact on the Public

Mr. Marcus was willing to testify as a witness for the Government, although the government did not call him. Accordingly, the agency considers Mr. Marcus' cooperation a favorable factor.

D. Prior Convictions

The agency is unaware of any additional convictions.

III. Proposed Action and Notice of Opportunity for a Hearing

Mr. Marcus' willingness to cooperate is outweighed by his leadership position within Halsey and, moreover, by the seriousness of Mr. Marcus' conduct with respect to public safety and the integrity of the drug approval process. Thus, based on the findings discussed above, and in particular the seriousness of Mr. Marcus' conduct with respect to the public safety and the integrity of the drug approval process, FDA proposes to issue an order under section 306(b)(2)(B) of the act debarring Mr. Marcus for a period of 5 years from providing services in any capacity to a person that has an approved or pending drug product application.

Under section 306(i) of the act and 21 CFR 10.50(c)(20), Mr. Marcus may request a hearing on disputed issues of material fact. Thus, in accordance with section 306 of the act and 21 CFR part 12, Mr. Marcus is hereby given notice of an opportunity for a hearing to show why he should not be debarred. If Mr. Marcus decides to seek a hearing, he must file a written notice of appearance and request for hearing on or before November 15, 1999. The procedures and requirements governing formal evidentiary hearings as applied to debarments are contained in 21 CFR part 12 and section 306(i) of the act.

Mr. Marcus' failure to file a timely written notice of appearance and request for hearing constitutes a waiver of his right to a hearing. If Mr. Marcus does not request a hearing in the manner prescribed by the regulations, the agency will not hold a hearing and will issue a final debarment order as proposed in this notice.

A request for a hearing may not rest upon mere allegations or denials but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. A hearing will be denied if the data and information Mr. Marcus submits, even if accurate, are insufficient to justify the factual determination urged. If it conclusively appears from the face of the information and factual analyses in Mr. Marcus' request for a hearing that there is no genuine and substantial issue of fact that would preclude the order of debarment, the Commissioner of Food and Drugs will deny Mr. Marcus' request for a hearing and enter a final order of debarment. The facts underlying Mr. Marcus' conviction are not at issue in this proceeding.

Mr. Marcus' request for a hearing, including any information or factual analyses relied on to justify a hearing, must be identified with Docket No. 99N–2674 and sent to the Dockets Management Branch (address above). Mr. Marcus must file four copies of all submissions pursuant to this notice of opportunity for hearing. 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.

This notice is issued under section 306 of the act and under authority delegated to the Director of the Center for Drug Evaluation and Research (21 CFR 5.99).

Dated: September 30, 1999.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 99–26938 Filed 10–14–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Food and Drug Administration/Industry Exchange Workshop on Medical Device Quality Systems Inspection Technique; Public Workshops; Addendum

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), is announcing an additional workshop in the series of FDA/Industry Exchange Workshops being conducted. The original list of workshops was published in the September 10, 1999 **Federal Register**. Topics for discussion include: Development of QSIT, Compliance Program and Warning Letter (Pilot), Management Controls, Corrective and Preventive Action, Design Controls, and Industry Perspective of QSIT. This additional workshop will enhance the medical device community's understanding of QSIT, and the device industry's establishment of effective quality systems, thereby preventing regulatory problems during inspections.

Date, Time, and Location: The workshop will be held on November 30 from 8:30 a.m. to 4:30 p.m. local time in Englewood, CO at the location in the chart below.

Registration: Send registration information (including name, title, firm name, address, telephone, and fax number) along with the correct payment amount to the Registrar. Fees cover refreshments, organization and site costs, and materials. Space is limited, therefore interested parties are encouraged to register early. Please arrive early to ensure prompt registration. If you need special accomodations due to a disability, please inform the Registrar at least 7 days in advance of the workshop. A sample registration form is provided at the end of this document.

Contact Person: Herman B. Janiger, U.S. Food and Drug Administration, Northeast Region, (HFRNE–17), 850 Third Ave., Brooklyn, New York 11232, 718–340–7000 ext. 5528.

SUPPLEMENTARY INFORMATION:

In the fall of 1999, FDA field offices will begin using the QSIT natiowide as the primary tool for medical device inspections. QSIT was developed using a collaborative effort with stakeholders and tested in the three districts. The additional workshop is scheduled as follows:

TABLE 1

Workshop Address	Date and Local Time	Deadline to Register and Fee	Registrar and Cosponsor	FDA Contact Person
ENGLEWOOD: Hilton Hotel, Denver Tech Center South, 7801 Orchard Rd., Englewood, CO 303–779–6161.	Tuesday, November 30, 1999, 8:30 a.m. to 4:30 p.m.	Tuesday, November 16, 1999, $170.00	Denise Rooney, Association of Food and Drug Officials, P.O. Box 3425, York PA 17402, 717–757–2888, FAX 717–755–8089	Brenda C. Baumert, Small Business Representative, Southwest Regional Office, 214–655–810, ext. 133.

The above workshop further implements the FDA Plan for Statutory Compliance (developed under section 406 of the FDA Modernization Act (21 U.S.C. 393)) through working more closely with stakeholders and ensuring access to needed scientific and technical expertise. It also complies with the Small Business Regulatory Enforcement Fairness Act (Public Law 104–121) that requires outreach activities by Government agencies directed to small businesses. This notice announcing the workshops and a registration form may also be accessed at the CDRH website at http://www.fda.gov/cdrh/fedregin.html. The following information is requested for registration:

BILLING CODE 4160–01–F