Debra A. Valentine,

General Counsel.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

[ATSDR–152]

Availability of Draft Toxicological Profiles

AGENCY: Agency for Toxic Substances and Disease Registry (ATSDR), Department of Health and Human Services (HHS).

ACTION: Notice of availability.

SUMMARY: The Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), as amended by the Superfund Amendments and Reauthorization Act of 1986 (SARA), section 104(i)(3) [42 U.S.C. 9604(i)(3)] directs the Administrator of ATSDR to prepare toxicological profiles of priority hazardous substances and to revise and publish each updated toxicological profile as necessary. This notice announces the availability of the 13th set of toxicological profiles, which consists of six updated drafts, prepared by ATSDR for review and comment.

DATES: In order to be considered, comments on these draft toxicological profiles must be received on or before February 22, 2000. Comments received after the close of the public comment period will be considered at the discretion of ATSDR based upon what is deemed to be in the best interest of the general public.

ADDRESSES: Requests for copies of the draft toxicological profiles should be sent to the attention of Ms. Loretta Norman, Division of Toxicology, Agency for Toxic Substances and Disease Registry, Mailstop E–29, 1600 Clifton Road, NE., Atlanta, Georgia 30333. Comments regarding the draft toxicological profiles should be sent to the attention of Dr. Ganga Choudhary, Division of Toxicology, Agency for Toxic Substances and Disease Registry, Mailstop E–29, 1600 Clifton Road, NE., Atlanta, Georgia 30333.

Requests for the draft toxicological profiles must be in writing, and must specifically identify the hazardous substance(s) profile(s) that you wish to receive. ATSDR reserves the right to provide only one copy of each profile requested, free of charge. In case of extended distribution delays, requestors will be notified.

Written comments and other data submitted in response to this notice and the draft toxicological profiles should bear the docket control number ATSDR–152. Send one copy of all comments and three copies of all supporting documents to Dr. Ganga Choudhary at the above stated address by the end of the comment period. Because all public comments regarding ATSDR toxicological profiles are available for public inspection, no confidential business or other confidential information should be submitted in response to this notice.

FOR FURTHER INFORMATION CONTACT: Ms. Loretta Norman, Division of Toxicology, Agency for Toxic Substances and Disease Registry, Mailstop E–29, 1600 Clifton Road, NE., Atlanta, Georgia 30333, telephone (404) 639–6322.

SUPPLEMENTARY INFORMATION: The Superfund Amendments and Reauthorization Act (SARA) (Pub. L. 99–499) amends the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or Superfund) (42 U.S.C. 9601 *et seq.*) by establishing certain responsibilities for the ATSDR and the Environmental Protection Agency (EPA) with regard to hazardous substances which are most commonly found at facilities on the CERCLA National Priorities List (NPL). Among these responsibilities is that the Administrator of ATSDR prepare toxicological profiles for substances included on the priority lists of hazardous substances. These lists identified 275 hazardous substances that ATSDR and EPA determined pose the most significant potential threat to human health. The availability of the revised priority list of 275 hazardous substances was announced in the **Federal Register** on November 17, 1997 (62 FR 61332). For prior versions of the list of substances see **Federal Register** notices dated April 17, 1987 (52 FR 12866); October 20, 1988 (53 FR 41280); October 26, 1989 (54 FR 43619); October 17, 1990 (55 FR 42067); October 17, 1991 (56 FR 52166); October 28, 1992 (57 FR 48801); February 28, 1994 (59 FR 9486); and April 29, 1996 (61 FR 18744). (CERCLA also requires ATSDR to assure the initiation of a research program to fill data needs associated with the substances.)

Section 104(i)(3) of CERCLA (42 U.S.C. 9604(i)(3)) outlines the content of these profiles. Each profile will include an examination, summary and interpretation of available toxicological information and epidemiologic evaluations. This information and these data are to be used to identify the levels of significant human exposure for the substance and the associated health effects. The profiles must also include a determination of whether adequate information on the health effects of each substance is available or in the process of development. When adequate information is not available, ATSDR, in cooperation with the National Toxicology Program (NTP), is required to assure the initiation of research to determine these health effects.

Although key studies for each of the substances were considered during the profile development process, this **Federal Register** notice seeks to solicit any additional studies, particularly unpublished data and ongoing studies, which will be evaluated for possible addition to the profiles now or in the future.

The following draft toxicological profiles will be made available to the public on or about October 17, 1999.

Document	Hazardous substance	CAS No.
1	ASBESTOS	001332–21–4
	AMOSITE ASBESTOS	012172–73–5
	CHRYSOTILE ASBESTOS	012001–29–5
2	BENZIDINE	000092–87–5
3	1,2-DICHLOROETHANE	000107–06–2
4	DI-N-BUTYL PHTHALATE	000084–74–2
5	METHYL PARATHION	000298–00–0
6	PENTACHLOROPHENOL	000087–86–5

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.

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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,