Toxicological profile	NTIS Order No.	CAS No.
3. Creosote	PB2003–100136	008001–58–9
Coal Tars	.....	008007–45–2
Coal Tar Pitch	.....	065996–93–2
4. DDT	PB2003–100137	000050–29–3
DDD	.....	000072–54–8
DDE	.....	000072–55–9
5. Di (2-ethylhexyl) phthalate	PB2003–100138	000117–81–7
6. Hexachlorobenzene	PB2003–100139	000118–74–1
7. Methoxychlor	PB2003–100140	000072–43–5

Dated: October 18, 2002.

Georgi Jones,

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

[FR Doc. 02–27085 Filed 10–23–02; 8:45 am]

BILLING CODE 4163–70–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

[ATSDR–187]

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 16th set of toxicological profiles, which consists of two new drafts and three 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 24, 2003. 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 printed copies or CD-ROMs of the draft toxicological profiles should be sent to the attention of Ms. Franchetta Stephens, Division of Toxicology, Agency for Toxic Substances and Disease Registry, Mailstop E–29, 1600 Clifton Road, NE, Atlanta, Georgia 30333. Electronic access to these documents is also available at the ATSDR website: *http://www.atsdr.cdc.gov/toxpro2.html.*

Comments regarding the draft toxicological profiles should be sent to the attention of Ms. Lori Miller, Division of Toxicology, Agency for Toxic Substances and Disease Registry, Mailstop E–29, 1600 Clifton Road, NE, Atlanta, Georgia 30333.

Requests for printed copies or CD-ROMs of 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–187. Send one copy of all comments and three copies of all supporting documents to Ms. Lori Miller 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 information or other confidential information should be submitted in response to this notice.

FOR FURTHER INFORMATION CONTACT: Ms. Franchetta Stephens, Division of Toxicology, Agency for Toxic Substances and Disease Registry, Mailstop E–29, 1600 Clifton Road, NE, Atlanta, Georgia 30333, telephone 1–888–422–8737 or (404) 498–0720.

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 U.S. 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 October 25, 2001 (66 FR 54014). 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); April 29, 1996 (61 FR 18744); November 17, 1997 (62 FR 61332) and October 21, 1999 (64 FR 56792). (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, 2002.

Document No. and hazardous substance	CAS No.
1. Ammonia and	007664–41–7
ammonia compounds	various
2. Chlorine dioxide	10049–04–4
3. Copper	007440–50–8
cupric sulfate	007758–98–7
4. Polybrominated biphenyls and	067774–32–7
polybrominated diphenyl ethers	various
5. Synthetic vitreous fibers	various

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 18, 2002.

Georgi Jones,

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

[FR Doc. 02–27086 Filed 10–23–02; 8:45 am]

BILLING CODE 4163–70–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 84F–0331]

Quest International; Withdrawal of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a future filing, of a food additive petition (FAP 4A3817) proposing that the food additive regulations be amended to provide for the safe use of white mineral oil as a component of defoaming agents for use in the brewing of beer.

FOR FURTHER INFORMATION CONTACT: Andrew Zajac, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy, College Park, MD 20740, 202–418–3095.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of October 25, 1984 (49 FR 42985), FDA announced that a food additive petition (FAP 4A3817) had been filed by J. E. Siebel Sons' Co., 4055 West Peterson Ave., Chicago, IL 60646. The petition proposed to amend the food additive regulations in § 173.340 *Defoaming agents* (21 CFR 173.340) to provide for the safe use of white mineral oil as defined by § 172.878(a) as a component of defoaming agents for use in the brewing of beer. On June 5, 2002, Quest International, 5115 Sedge Blvd., Hoffman Estates, IL 60192, informed FDA in writing that they had acquired J. E. Siebel Sons' Co. and had rights to FAP 4A3817. Quest International has now withdrawn the petition without prejudice to a future filing (21 CFR 171.7).

Dated: October 9, 2002.

Alan M. Rulis,

Director, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition.

[FR Doc. 02–27047 Filed 10–23–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01E–0363]

Determination of Regulatory Review Period for Purposes of Patent Extension; MIFEPREX; Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending a previous determination of the regulatory review period for MIFEPREX that appeared in the **Federal Register** of January 25, 2002 (67 FR 3724). The agency is taking this action in response to received comments. FDA is publishing notice of that amendment as required by law.

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.

FOR FURTHER INFORMATION CONTACT: Claudia V. Grillo, Office of Regulatory Policy (HFD–007), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4565.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 25, 2002 (67 FR 3724), FDA published its determination of the regulatory review period for MIFEPREX. On June 10, 2002, Corcept Therapeutics, Inc., (Corcept) filed a request for revision of the regulatory review period. On July 2, 2002, the applicant filed a comment, disagreeing with Corcept's request and maintaining that FDA's initial determination was correct.

The basis of Corcept's request is that August 4, 1994, is not the correct date an investigational new drug application (IND) covering the approved drug product became effective. Corcept asserts that June 13, 1983, is the appropriate date. FDA has re-examined its records and has determined that Corcept is correct. The date an exemption under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) became effective is June 13, 1983.

The agency, the applicant, and Corcept agree that the relevant IND is IND 22,047. All agree that IND 22,047 became effective in 1983.

The applicant's argument for keeping the initial determination is based on the claim that August 4, 1994, represents the date the IND first covered the ''approved human drug product.'' While acknowledging that IND 22,047 became effective in 1983, the applicant observes that during the next several years the only studies conducted were studies of mifepristone alone, that is, not in conjunction with the administration of other drugs. The 1994 date is when the applicant submitted an amendment to IND 22,047 to initiate studies of mifepristone when followed by the later