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