

**Food and Drug Administration**

[Docket No. 76N-0462]

**American Cyanamid Co.; Refusal To Approve Supplemental New Animal Drug Application; Availability of the Commissioner's Decision****AGENCY:** Food and Drug Administration.**ACTION:** Notice of availability of Commissioner's decision.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that the Commissioner of Food and Drugs has issued his final decision concerning a supplemental new animal drug application (NDA) for Proban Cythioate Oral Liquid, 1.6% ("Proban") submitted by the American Cyanamid Co. The Commissioner has determined that the supplemental NDA for Proban should not be approved. The decision therefore affirms the initial decision of the Administrative Law Judge, which held that the submission seeking Proban's approval failed to satisfy the Federal Food, Drug, and Cosmetic Act's safety and effectiveness requirements for new animal drugs. Differences between the Commissioner's and the Administrative Law Judge's opinions are specifically identified in the Commissioner's decision.

**DATE:** Effective June 20, 1984.

**ADDRESS:** The Commissioner's decision, including the final order, and all other documents related to the decision, may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

**FOR FURTHER INFORMATION CONTACT:** Theodore E. Herman, Regulations Policy Staff (HFC-10), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-34880.

**SUPPLEMENTARY INFORMATION:** This notice is issued in accordance with 21 CFR 12.130(e).

Dated: June 21, 1984.

William F. Randolph,  
Acting Associate Commissioner for  
Regulatory Affairs.

[FR Doc. 84-17040 Filed 6-22-84; 11:06 am]

BILLING CODE 4160-01-M

[Docket No. 84C-0192]

**DOW Corning Ophthalmics, Inc.; Filing of Color Additive Petition****AGENCY:** Food and Drug Administration.**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing

that Dow Corning Ophthalmics, Inc., has filed a color additive petition proposing that the color additive regulations be amended to provide for the safe use of 4-[(2,4-dimethylphenyl)azo]-2,4-dihydro-5-methyl-2-phenyl-3H-pyrazol-3-one for coloring silicone resin contact lenses.

**FOR FURTHER INFORMATION CONTACT:** Andrew D. Laumbach, Center for Food Safety and Applied Nutrition (formerly Bureau of Foods) (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5690.

**SUPPLEMENTARY INFORMATION:** Under the Federal Food, Drug, and Cosmetic Act (sec. 706(b)(1), 74 Stat. 399-402 as amended (21 U.S.C. 376(b)(1))), notice is given that a color additive petition (CAP 4C0180) has been filed by Dow Corning Ophthalmics, Inc., P.O. Box 1767, Midland, MI 48640, proposing that the color additive regulations be amended to provide for the safe use of 4-[(2,4-dimethylphenyl)azo]-2,4-dihydro-5-methyl-2-phenyl-3H-pyrazol-3-one for coloring silicone resin contact lenses.

The agency has carefully considered the potential environmental effects of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 20, 1984.

Richard J. Ronk,  
Acting Director, Center for Food Safety and  
Applied Nutrition.

[FR Doc. 84-17044 Filed 6-26-84; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 84F-0216]

**Halssen & Lyon; Filing of Food Additive Petition****AGENCY:** Food and Drug Administration.**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that Halssen & Lyon has filed a petition proposing that the food additive regulations be amended to provide for the safe use of ethyl acetate as a solvent in the decaffeination of tea.

**FOR FURTHER INFORMATION CONTACT:** Patricia J. McLaughlin, Center for Food Safety and Applied Nutrition (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5690.

**SUPPLEMENTARY INFORMATION:** Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5), 72 Stat. 1786 (21 U.S.C. 348(b)(5))), notice is given that a petition (FAP 4A3804) has been filed by Halssen & Lyon, c/o Pine Consultants, Inc., 1905 Pine St., Philadelphia, PA 19103, proposing that § 173.228 *Ethyl acetate* (21 CFR 173.228) be amended to provide for the safe use of ethyl acetate as a solvent in the decaffeination of tea.

The potential environmental impact of this action is being reviewed. If the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the *Federal Register* in accordance with 21 CFR 25.40(c) (proposed December 11, 1979; 44 FR 71742).

Dated: June 20, 1984

Richard J. Ronk,  
Acting Director, Center for Food Safety and  
Applied Nutrition.

[FR Doc. 84-17045 Filed 6-25-84; 8:45 am]

BILLING CODE 4160-01-M

**Public Health Service****National Toxicology Program Board of Scientific Counselors' Meeting**

Pursuant to Pub. Law 92-463, notice is hereby given of the meeting of the National Toxicology Program Board of Scientific Counselors, U.S. Public Health Service, in the Conference Center, Building 101, South Campus, National Institute of Environmental Health Sciences, Research Triangle Park, North Carolina, on July 26, 1984.

The meeting will be open to the public from 10:30 a.m. until adjournment for the purpose of providing peer review of the data from the chronic carcinogenesis bioassay of D & C Red No. 33 in Charles River CD-1 mice and Charles River Sprague Dawley rats. The bioassay was sponsored by the Pharmaceutical Manufacturers Association, conducted by International Research and Development Corporation, and submitted to the Food and Drug Administration (FDA) in support of permanent listing of D & C Red No. 33. The review will be conducted by the Technical Reports Review Subcommittee of the Board in conjunction with an *ad hoc* panel of experts.

The meeting will commence with a brief overview of the studies. This will be followed with presentations by scientific staff from the Center for Food



Safety and Applied Nutrition, FDA, concerning the pathology findings. Sufficient time will be allowed for public comment.

The Executive Secretary, Dr. Larry G. Hart, Office of the Director, National Toxicology Program, P.O. Box 12233, Research Triangle Park, North Carolina 27709, telephone (919) 541-3971, FTS 629-3971, will furnish program information prior to the meeting and summary minutes subsequent to the meeting.

Dated: June 20, 1984.

David P. Rall,

Director, National Toxicology Program.

[FR Doc. 84-17046 Filed 6-26-84; 8:45 am]

BILLING CODE 4140-01-M

### National Toxicology Program Board of Scientific Counselors; Meeting

Pursuant to Pub. L. 92-463, notice is hereby given of a meeting of the National Toxicology Program (NTP) Board of Scientific Counselors, U.S. Public Health Service, in the Conference Center, Building 101, South Campus, National Institute of Environmental Health Sciences, Research Triangle Park, North Carolina, on July 27, 1984.

The meeting will be open to the public from 9:00 a.m. until adjournment. The primary agenda item is the completion of peer review on draft technical reports of long-term toxicology and carcinogenesis studies from the National Toxicology Program. Reviews will be conducted by the Technical Reports Review Subcommittee of the Board in conjunction with an *ad hoc* panel of experts.

Draft technical reports on the following chemicals (listed alphabetically with Chemical Abstracts Service registry numbers, routes of administration, and NTP chemical managers for each study) are scheduled to be peer reviewed on July 27. Since NTP policy requires that a data audit be performed with a summary of the audit report included in the appendix of the technical report prior to peer review, there is the possibility that not all of the technical reports listed below will be reviewed at this meeting.

Chemical (CAS Registry No.)	Route	Chemical manager (telephone No.)
Asbestos, Chrysotile (12001-29-5)	Feed	Dr. E. E. McConnell (919-541-3267)
Benzenes (72-43-2)	Gavage	Dr. J. E. Huff (919-541-3780)
2-Chloroethanol (107-07-3)	Dermal	Dr. D. Goldman (202-382-7835)
1,3-Dichloropropene (Telone II) (542-75-8)	Gavage	Dr. R. Yang (919-541-2947)

Chemical (CAS Registry No.)	Route	Chemical manager (telephone No.)
Dimethyl Hydrogen Phosphite (868-85-9)	Gavage	Dr. J. Dunnick (919-541-4811)
HC Blue No. 2 (33229-34-4)	Feed	Dr. J. Mennear (919-541-4178)

In addition, the technical report on the toxicology and carcinogenesis studies of 1,1,1-trichloroethane (methylchloroform) (CAS No. 71-55-6) is being revised. If completed in time for the meeting a re-review will be done. This report was reviewed and approved by the Panel in February 1983. However, the subsequent data audit resulted in sufficient changes such that the NTP considers another peer review necessary.

The Executive Secretary, Dr. Larry G. Hart, Office of the Director, National Toxicology Program, P.O. Box 12233, Research Triangle Park, North Carolina 27709, telephone (919-541-3971), FTS (629-3971), will furnish final agenda, rosters of subcommittee and panel members, and other program information prior to the meeting, and summary minutes subsequent to the meeting.

Dated: June 20, 1984.

David P. Rall, M.D., Ph.D.,

Director, National Toxicology Program.

[FR Doc. 84-17047 Filed 6-26-84; 8:45 am]

BILLING CODE 4140-01-M

### DEPARTMENT OF THE INTERIOR

#### Bureau of Land Management

#### Canon City, Colorado, District Advisory Council; Meeting

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Canon City District Advisory Council Meeting.

**SUMMARY:** Notice is hereby given in accordance with Pub. L. 94-579 that a meeting of the Canon City District Advisory Council will be held on Thursday and Friday, July 19 and 20, 1984.

The Council will meet from 1 p.m. to 5 p.m. on July 19 at the Chaffee County Bank Building, 146 G Street, Salida, Colorado. On July 20th from 8 a.m. to 1 p.m. a field trip to view recreation and other uses of public lands along the Arkansas River is planned.

The meeting agenda will include:

1. The Northeast Resource Area Draft Resource Management Plan and Environmental Impact Statement.
2. Briefing on Cooperative Management Agreements.

3. Public presentations to the Council (open invitation).

The meeting is open to the public, transportation for the field trip is the responsibility of the individual. Persons interested may make oral presentations to the Council between 1:30 p.m. Thursday July 19, or they may file written statements for the Council's consideration. The District Manager may limit the length of oral presentations depending on the number of people wishing to speak.

**ADDRESS:** Anyone wishing to make a presentation to the Council orally or in writing should notify the District Manager, Bureau of Land Management, 3080 East Main (P.O. Box 311), Canon City, Colorado 81212 by July 18, 1984.

#### SUPPLEMENTARY INFORMATION:

Summary minutes of the meeting will be available for public inspection and reproduction during regular working hours at the District Office approximately 30 days following the meeting.

#### FOR FURTHER INFORMATION CONTACT:

Glen Wallace, (303) 275-0631.

Donnie R. Sparks,

District Manager.

[FR Doc. 84-17024 Filed 6-26-84; 8:45 am]

BILLING CODE 4310-JB-M

### [C-35468 and C-36846]

#### Realty Action; Noncompetitive Sale of Public Lands in Chaffee County, Colorado

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Notice of Realty Action C-35468 and C-36846. Noncompetitive Sale of Public Lands in Chaffee County, Colorado.

**SUMMARY:** The following described land has been examined and identified as suitable for disposal by sale under Section 203 of the Federal Land Policy and Management Act of 1976 (90 Stat. 2750, 43 U.S.C. 1713) at no less than the appraised fair market value:

Serial No.	Parcel	Legal description	Acreage	Appraised value
C-35468	368B	Sixth Principal Meridian, Colorado, T. 11 S., R. 79 W., sec. 31, lots 59 (0.79), 60 (0.34), 61 (0.64), 70 (2.65)	4.42	\$6,200
C-36846	368A	T. 12 S., R. 79 W., sec. 34, SW 1/4 SW 1/4	20.00	\$34,850

Parcel 368B is being offered to Walter Maass and Parcel 368A to Franklin