Dated: September 17, 1998.

**William K. Hubbard,**

*Associate Commissioner for Policy Coordination.*

[FR Doc. 98–25641 Filed 9–24–98; 8:45 am]

**BILLING CODE 4160–01–F**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 98C–0790]**

### EM Industries, Inc.; Filing of Color Additive Petition

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that EM Industries, Inc., has filed a petition proposing that the color additive regulations be amended to provide for the safe use of synthetic iron oxide and mica to color food and to provide for the safe use of titanium dioxide to color food at levels higher than the current limit.

**FOR FURTHER INFORMATION CONTACT:** Aydin Örstan, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3076.

**SUPPLEMENTARY INFORMATION:** Under the Federal Food, Drug, and Cosmetic Act (sec. 721(d)(1) (21 U.S.C. 379e(d)(1))), notice is given that a color additive petition (CAP 8C0262) has been filed by EM Industries, Inc., 7 Skyline Dr., Hawthorne, NY 10532. The petition proposes to amend the color additive regulations to provide for the safe use of synthetic iron oxide and mica to color food and to provide for the safe use of titanium dioxide to color food at levels higher than the current limit.

The agency has determined under 21 CFR 25.32(r) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: September 4, 1998.

**Laura M. Tarantino,**

*Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.*

[FR Doc. 98–25638 Filed 9–24–98; 8:45 am]

**BILLING CODE 4160–01–F**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 98N–0787]**

### Parke-Davis Pharmaceutical Research et al.; Withdrawal of Approval of 14 New Drug Applications and 13 Abbreviated New Drug Applications

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is withdrawing approval of 14 new drug applications (NDA's) and 13 abbreviated new drug applications (ANDA's). The holders of the applications notified the agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

**EFFECTIVE DATE:** September 25, 1998.

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

**SUPPLEMENTARY INFORMATION:** The holders of the applications listed in the table in this document have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications. The applicants have also, by their request, waived their opportunity for a hearing.

| Application No. | Drug | Applicant |
|---|---|---|
| NDA 3–402 | Pitressin Tannate in Oil (Vasopressin Tannate), 5 Pressor Units, 1 milliliter | Parke-Davis Pharmaceutical Research, 2800 Plymouth Rd., Ann Arbor, MI 48105. |
| NDA 6–212 | Propylthiouracil Tablets | Abbott Laboratories, 100 Abbott Park Rd., Abbott Park, IL 60064. |
| NDA 10–355 | Quarzan (clindium bromide) Capsules | Hoffmann-LaRoche Inc., 340 Kingsland St., Nutley, NJ 07110–1199. |
| NDA 12–184 | Norlutate (Norethindrone Acetate) 5-milligram (mg) Tablets | Parke-Davis Pharmaceuticals, 2800 Plymouth Rd., Ann Arbor, MI 48105. |
| NDA 12–470 | Akrinol Cream | Schering-Plough Corp., 2000 Galloping Hill Rd., Kenilworth, NJ 07033. |
| NDA 13–294 | Azo-Gantanol (sulfa-methoxazole and phenazo-pyridine hydro-chloride) Tablets | Hoffmann-La Roche Inc. |
| NDA 16–020 | Symmetrel (amantadine hydro-chloride) Capsules, 100 mg | Endo Pharmaceuticals, Inc., 500 Endo Blvd., Garden City, NY 11530. |
| NDA 16–191 | Sorbitrate (isosorbide dinitrate) Sublingual Tablets, 2.5 and 5 mg | Zeneca Pharmaceuticals, a business unit of Zeneca, Inc., 1800 Concord Pike, P.O. Box 15437, Wilmington, DE 19850–5437. |
| NDA 17–117 | Symmetrel (amantadine hydro-chloride) Capsules | Endo Pharmaceuticals, Inc. |
| NDA 17–552 | Tylenol Acetminophen Extra Strength Tablets, 500 mg | McNeil Consumer Products Co., 7050 Camp Hill Rd., Fort Washington, PA 19034–2299. |
| NDA 18–179 | Valrelease (diazepam) Capsules | Hoffman-LaRoche Inc. |
| NDA 50–345 | Cordran N Ointment (flurandrenolide) | Lilly Research Laboratories. |
| NDA 50–346 | Cordran N Cream (flurandrenolide) | Do. |
| NDA 50–379 | Sterile Ophthalmic Solution Neo-Hydeltrasol (neomycin sul-fate-prednisolone sodium phosphate ophthalmic solution) | Merck & Co., Inc., P.O. Box 4, BLA–20, West Point, PA 19486. |
| ANDA 62–385 | Neomycin Sulfate Powder, USP (for compounding oral prod-ucts) | Paddock Laboratories, Inc., 3940 Quebec Ave. North, Min-neapolis, MN 55427. |

| Application No. | Drug | Applicant |
|---|---|---|
| ANDA 62–455 | Polymyxin B Sulfate, USP (for prescription compounding) | Do. |
| ANDA 62–456 | Bacitracin Powder, USP (for prescription compounding) | Do. |
| ANDA 74–084 | Diltiazem Hydrochloride Tablets USP, 30 mg and 60 mg | Novopharm N.C., Inc., agent for Novopharm Ltd., 4700 Novopharm Blvd., Wilson, NC 27893. |
| ANDA 74–511 | SULSTER (Sulfacetamide Sodium and Prednisolone Sodium Phosphate Ophthalmic Solution, 10%/eq. 0.23% phosphate) | Taylor Pharmaceuticals (an Akorn Co.), 150 South Wyckles Rd., P.O. Box 1220, Decatur, IL 62525–1220. |
| ANDA 80–025 | Sulf-10 (Sulfacetamide Sodium Ophthalmic Solution, USP) 10% | Ciba Vision, 11460 Johns Creek Pkwy., Duluth, GA 30097–1556. |
| ANDA 83–648 | Meprotabs (Meprobamate Tablets USP, 400 mg) | Wallace Laboratories, Division of Carter-Wallace, Inc., Half Acre Rd., P.O. Box 1001, Cranberry, NJ 08512–0181. |
| ANDA 85–136 | Methocarbamol Tablets USP (750 mg) | Forest Laboratories, Inc., 909 Third Ave., New York, NY 10022–4731. |
| ANDA 85–137 | Methocarbamaol Tablets USP (500 mg) | Inwood Laboratories, Inc., 909 Third Ave., New York, NY 10022–4731. |
| ANDA 86–228 | Nitroglycerin Extended-release Capsules (2.5 mg) | Geneva Pharmaceuticals, Inc., 2655 West Midway Blvd., P.O. Box 446, Broomfield, CO 80038–0446. |
| ANDA 86–230 | Nitroglycerin Extended-release Capsules (6.5 mg) | Do. |
| ANDA 87–797 | Triamcinolone Acetonide Cream USP, 0.025% | Alpharma USPD, Inc., 333 Cassell Dr., suite 3500, Baltimore, MD 21224. |
| ANDA 88–220 | Nitroglycerin Extended-release Capsules (9 mg) | Geneva Pharmaceuticals, Inc. |

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) and under authority delegated to the Director, Center for Drug Evaluation and Research (21 CFR 5.82), approval of the applications listed in the table in this document, and all amendments and supplements thereto, is hereby withdrawn, effective September 25, 1998.

Dated: September 14, 1998.

**Janet Woodcock,**

*Director, Center for Drug Evaluation and Research.*

[FR Doc. 98–25713 Filed 9–24–98; 8:45 am]

**BILLING CODE 4160–01–F**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 97N–0503]**

### Agency Information Collection Activities; Announcement of OMB Approval; New Animal Drug Application (NADA), Form FDA 356 V, 21 CFR Part 514

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''New Animal Drug Application (NADA), Form FDA 356 V, 21 CFR Part 514'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

**FOR FURTHER INFORMATION CONTACT:** Denver Presley, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of June 9, 1998 (63 FR 31505), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (44 U.S.C. 3507). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0032. The approval expires on July 31, 2001.

Dated: September 17, 1998.

**William K. Hubbard,**

*Associate Commissioner for Policy Coordination.*

[FR Doc. 98–25642 Filed 9–24–98; 8:45 am]

**BILLING CODE 4160–01–F**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Government-Owned Inventions; Availability for Licensing

**AGENCY:** National Institutes of Health, Public Health Service, DHHS.

**ACTION:** Notice.

**SUMMARY:** The inventions listed below are owned by agencies of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

**ADDRESSES:** Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7057; fax: 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

**Water Soluble Drugs and Methods of Preparing Same**

DK Ho et al. (SAIC/NCI)
Serial No. 60/093,284 filed 17 Jul 98
Licensing Contact: Girish Barua, 301/496–7056, ext. 263

Many potential drugs of cancer chemotherapy intended for parenteral administration have been abandoned because the active ingredient is slightly soluble or water-insoluble. Various methods have been developed to allow these drugs to be dissolved in water; however, these methods can be complex and have negative impacts resulting from the use of cosolvents and complexing agents. The present invention addresses these problems by providing a method of producing water-soluble analogues of water-insoluble drugs through derivatization and conjugation with a polar moiety via a thiol ether bond with a