

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN <sup>1</sup>

21 CFR section	No. of recordkeepers	Annual frequency of record-keeping	Total annual records	Hours per record	Total hours
1002.30 and 1002.31(a)	1,150	1,655.5	1,903,825	198.7	228,505
1002.40 and 1002.41	2,950	49.2	145,140	2.4	7,080
1002.30(g)(2)	22	1	22	0.5	11
1040.10(a)(3)(ii)	83	1	83	1	83
Total					235,679

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

The burden estimates were derived by consultation with FDA and industry personnel and actual data collected from industry over the past 3 years. An evaluation of the type and scope of information requested was also used to derive some time estimates. For example, disclosure information primarily requires time only to update and maintain existing manuals. Initial development of manuals has been performed except for new firms entering the industry. When information is generally provided to users, assemblers, or dealers in the same manual, they have been grouped together in the "Estimated Annual Reporting Burden" table.

The following information collection requirements are not subject to review by OMB because they do not constitute a "collection of information" under the PRA: Sections 1002.31(c); 1003.10(a), (b), and (c); 1003.11(a)(3) and (b); 1003.20(a) through (h); 1003.21(a) through (d); 1003.22(a) and (b); 1003.30(a) and (b); 1003.31(a) and (b); 1004.2(a) through (i); 1004.3(a) through (i); 1004.4(a) through (h); and 1005.21(a) through (c). These requirements "apply to the collection of information during the conduct of general investigations or audits" (5 CFR 1320.4(b)). The following labeling requirements are also not subject to review under the PRA because they are a public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public (5 CFR 1320.3(c)(2)): Sections 1020.10(c)(4), 1030.10(c)(6), 1040.10(g), 1040.30(c)(1), and 1050.10(d)(1).

Dated: September 7, 2000.

**William K. Hubbard,**

*Senior Associate Commissioner for Policy, Planning, and Legislation.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 00F-1482]

#### Electric Power Research Institute, Agriculture and Food Technology Alliance; Filing of Food Additive Petition

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that the Electric Power Research Institute, Agriculture and Food Technology Alliance has filed a petition proposing that the food additive regulations be amended to provide for the safe use of ozone in gaseous and aqueous phases as an antimicrobial agent for the treatment, storage, and processing of foods.

#### FOR FURTHER INFORMATION CONTACT:

Robert L. Martin, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3074.

**SUPPLEMENTARY INFORMATION:** Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 0A4721) has been filed by the Electric Power Research Institute, Agriculture and Food Technology Alliance, 2747 Hutchinson Ct., Walnut Creek, CA 94598. The petition proposes to amend the food additive regulations in part 173 Secondary Direct Food Additives Permitted in Food for Human Consumption (21 CFR part 173) to provide for the safe use of ozone in gaseous and aqueous phases as an antimicrobial agent for the treatment, storage, and processing of foods.

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: August 23, 2000.

**Alan M. Rulis,**

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

[FR Doc. 00-23405 Filed 9-12-00; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 00N-1498]

#### Lilly Research Laboratories et al.; Withdrawal of Approval of 28 New Drug Applications

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is withdrawing approval of 28 new drug applications (NDA'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.

**DATES:** Effective September 30, 2000.

#### 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 4-038	Diethylstilbestrol (DES) Injection.	Lilly Research Laboratories, Lilly Corporate Center, Indianapolis, IN 46285.
NDA 4-039	DES Tablets.	Do.
NDA 4-040	DES Suppository.	Do.
NDA 4-041	DES Tablets.	Do.
NDA 4-056	Stilbetin Tablets (Diethylstilbestrol Tablets USP).	Bristol-Myers Squibb Co., P.O. Box 4000, Princeton, NJ 08543-4000.
NDA 6-327	Isuprel (Isoproterenol Hydrochloride) Inhalation Solution.	Sanofi-Synthelabo, Inc., 90 Park Ave., New York, NY 10016-1389.
NDA 7-371	Mecostin Injection (Dimethyl Tubocurarine Chloride).	Bristol-Myers Squibb Co.
NDA 8-392	Nydrazid (Isoniazid USP) Tablets, Syrup, Capsules.	Do.
NDA 9-052	Rezipas (Aminosalicylic Acid Resin Powder).	Do.
NDA 9-273	Rauwolfia Serpentina, 50-milligram (mg) and 100-mg Tablets, 35-mg Capsule.	Impax Laboratories, Inc., 30831 Huntwood Ave., Hayward, CA 94544.
NDA 9-627	Reserpine, 0.1-mg, 0.25-mg, 0.5-mg, and 1-mg Tablets.	Do.
NDA 10-010	Stilphostrol (Diethylstilbestrol Diphosphate) Injection and Tablets.	Bayer Corp., 400 Morgan Lane, West Haven, CT 06516-4175.
NDA 10-347	Delalutin (Hydroxyprogesterone Caproate Injection USP).	Bristol-Myers Squibb Co.
NDA 11-359	Ora-testryl (Fluoxymesterone Tablets USP).	Do.
NDA 11-642	Cardioquin (Quinidine Polygalacturonate) 275-mg Tablets.	Purdue Frederick Co., 100 Connecticut Ave., Norwalk, CT 06850-3590.
NDA 11-745	Konakion (Phytonadione) Injection.	Hoffman-La Roche, Inc., 340 Kingsland St., Nutley, NJ 07110.
NDA 12-248	Plegine (Phendimetrazine Tartate) Tablets.	Wyeth Ayerst Laboratories, P.O. Box 8299, Philadelphia, PA 19101-8299.
NDA 12-339	Bronkometer (Isoetharine Mesylate Inhalation Aerosol) and Bronkosol (Isoetharine Hydrochloride Inhalation Solution).	Sanofi-Synthelabo, Inc.
NDA 16-911	Delalutin (Hydroxyprogesterone Caproate Injection USP).	Bristol-Myers Squibb Co.
NDA 17-424	Septisol Foam (Hexachlorophene).	Steris Corp., P.O. Box 147, St. Louis, MO 63166-0147.
NDA 18-672	Nitro IV 5 mg/milliliters (mL) Injection and Nitronal Injection.	G. Pohl-Boskamp GmbH & Co., Kieler Strasse 11, D-25551 Hohenlockstedt, Germany.
NDA 18-762	Brethaire (Terbutaline Sulfate) Inhalation Aerosol.	Novartis Pharmaceuticals Corp., 59 Route 10, East Hanover, NJ 07936-1080.
NDA 19-069	Mycelex (Clotrimazole) Vaginal Tablets.	Bayer Corp.
NDA 19-082	Dalgan (Dezocine) Injection, 5, 10, and 15 mg/mL.	AstraZeneca LP, 725 Chesterbrook Blvd., Wayne, PA 19087-5677.
NDA 19-174	Trandate HCT (Labetalol Hydrochloride/Hydrochlorothiazide) Tablets.	Glaxo Wellcome, Inc., P.O. Box 13398, Research Triangle Park, NC 27709.
NDA 19-287	DIZAC (Diazepam Injectable Emulsion).	Pharmacia & Upjohn, 7000 Portage Rd., Kalamazoo, MI 49001-0199.
NDA 20-559	Tritec (Ranitidine Bismuth Citrate) Tablets.	Glaxo Wellcome, Inc.
NDA 21-048	17 $\beta$ -Estradiol Transdermal System.	R. W. Johnson Pharmaceutical Research Institute, 920 Route 202 South, P.O. Box 300, Raritan, NJ 08869-0602.

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 30, 2000.

Dated: September 5, 2000.

**Janet Woodcock,**

*Director, Center for Drug Evaluation and Research.*

[FR Doc. 00-23477-Filed 9-12-00; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 00D-1497]

#### **Draft Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #4; Availability**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Compliance Guidance: The Mammography Quality Standards Act

Final Regulations Document #4." This draft guidance is neither final nor is it in effect at this time. The final regulations implementing the Mammography Quality Standards Act of 1992 (the MQSA) became effective April 28, 1999. The draft guidance document is intended to help facilities and their personnel meet the MQSA final regulations.

**DATES:** Submit written comments concerning this draft guidance by December 12, 2000.

**ADDRESSES:** Submit written requests for single copies on a 3.5" diskette of the draft guidance entitled "Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #4" to the Division of Small