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 through (d); 1003.3 through (d); 1004.4(a) through (h); 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).

William K. Hubbard,
Senior Associate Commissioner for Policy, Planning, and Legislation.

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.


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.

Alan M. Rulis,
Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

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.


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.
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.


Janet Woodcock,
Director, Center for Drug Evaluation and Research.

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

BILLING CODE 4160–01–F

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