heat processes or other means of preservation.

To protect the public health, FDA's regulations require that each firm that manufactures, processes, or packs acidified foods or thermally processed low-acid foods in hermetically sealed containers for introduction into interstate commerce register the establishment with FDA using Form FDA 2541 (§§ 108.25(c)(1) and 108.35(c)(2) (21 CFR 108.25(c)(1) and 108.35(c)(2))). In addition to registering the plant, each firm is required to provide data on the processes used to produce these foods, using Form FDA 2541a for all methods except aseptic processing, or Form FDA 2541c for aseptic processing of low-acid foods in hermetically sealed containers (§§ 108.25(c)(2) and 108.35(c)(2)). Plant registration and process filing may be accomplished simultaneously. Process data must be filed prior to packing any new product, and operating processes and procedures must be posted near the processing equipment or made available to the operator (21 CFR 113.87(a)).

Regulations in parts 108, 113, and 114 (21 CFR parts 108, 113, and 114) require firms to maintain records showing adherence to the substantive requirements of the regulations. These records must be made available to FDA on request. Firms are also required to document corrective actions when process controls and procedures do not fall within specified limits (§§ 113.89, 114.89, and 114.100(c)); to report any instance of potential health-endangering spoilage, process deviation, or contamination with microorganisms where any lot of the food has entered distribution in commerce (§§ 108.25(d) and 108.35(d) and (e)); and to develop and keep on file plans for recalling products that may endanger the public health (§§ 108.25(e) and 108.35(f)). To permit lots to be traced after distribution, acidified foods and thermally processed low-acid foods in hermetically sealed containers must be marked with an identifying code (§§ 113.60(c) (thermally processed foods) and 114.80(b) (acidified foods)).

FDA estimates the burden of complying with the information collection provisions of the agency's regulations for acidified foods and thermally processed low-acid foods in hermetically sealed containers as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Form No.	21 CFR Section	No. of Respondents	Annual Frequency of Response	Total Annual Responses	Hours per Response	Total Hours
FDA 2541 (registration)	108.25 and 108.35	500	1	500	.17	85
FDA 2541a (process filing)	108.25 and 108.35	1,000	7	7,000	.333	2,331
FDA 2541c (process filing)	108.35	275	2	550	.75	412
Total				8,050		2,828

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Part	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
108, 113, and 114	6,000	1	6,000	250	1,500,000

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

The reporting burden for §§ 108.25(d) and 108.35(d) and (e) is insignificant because notification of spoilage, process deviation or contamination of product in distribution occurs less than once a year. Most firms discover these problems before the product is distributed and, therefore, are not required to report the occurrence. To avoid double-counting, estimates for §§ 108.25(g) and 108.35(h) have not been included because they merely cross-reference recordkeeping requirements contained in parts 113 and 114.

Dated: July 15, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–18319 Filed 7–19–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0012]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Postmarketing Adverse Drug Experience Reporting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Submit written comments on the collection of information by August 21, 2002.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Stuart Shapiro, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Postmarketing Adverse Drug Experience Reporting—21 CFR 310.305 and 314.80 (OMB Control Number 0910–0230)—Extension

Sections 201, 502, 505, and 701 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321, 352, 355, and 371) require that marketed drugs be safe and effective. In order to know whether drugs that are not safe and effective are on the market, FDA must be promptly informed of adverse experiences occasioned by the use of marketed drugs. In order to help ensure this, FDA issued regulations (§§ 310.305 and 314.80 (21 CFR 310.305 and 314.80)) to impose reporting and recordkeeping requirements on the drug industry that would enable FDA to take action necessary for protection of the public health from adverse drug experiences.

All applicants who have received marketing approval of drug products are required to report to FDA serious, unexpected adverse drug experiences, as well as followup reports when needed (§ 314.80(c)(1)). This includes reports of all foreign or domestic adverse experiences as well as those obtained in scientific literature and from postmarketing epidemiological/surveillance studies. Under § 314.80(c)(2) applicants must provide periodic reports of adverse drug experiences. A periodic report includes, for the reporting interval, reports of serious, expected adverse drug experiences and all nonserious adverse drug experiences, a narrative summary and analysis of adverse drug experiences and a history of actions taken because of adverse drug experiences. Under § 314.80(i) applicants must keep for 10 years records of all adverse drug experience reports known to the applicant.

For marketed prescription drug products without approved new drug applications (NDAs) or abbreviated new drug applications, manufacturers, packers, and distributors are required to report to FDA serious, unexpected adverse drug experiences as well as followup reports when needed (§ 310.305(c)). Under § 310.305(f) each manufacturer, packer, and distributor shall maintain for 10 years records of all adverse drug experiences required to be reported.

The primary purpose of FDA's adverse drug experience reporting system is to provide a signal for potentially serious safety problems with marketed drugs. Although premarket testing discloses a general safety profile of a new drug's comparatively common adverse effects, the larger and more diverse patient populations exposed to the marketed drug provides, for the first time, the opportunity to collect information on rare, latent, and long-term effects. Signals are obtained from a variety of sources, including reports from patients, treating physicians, foreign regulatory agencies, and clinical investigators. Information derived from the adverse drug experience reporting system contributes directly to increased public health protection because the information enables FDA to make important changes to the product's labeling (such as adding a new warning) and when necessary, to initiate removal of a drug from the market.

In the **Federal Register** of February 25, 2002 (67 FR 8545), the agency requested comments on the proposed collection of information. FDA received two comments.

The comments asked what methodology and assumptions were used by FDA to calculate the burden estimates.

The ''hours per response'' were based on FDA's estimates of the time it would take manufacturers, packers, distributors, and applicants of marketed human drug products to submit the information to the agency.

The comments said that the annual number of responses of periodic reports is significantly underestimated. One comment estimated that companies submit more than 400 periodic reports (annual and quarterly reports) annually. The other comment estimated that it submits over 70 periodic reports annually.

FDA data indicates that it receives, on average, approximately 10,245 periodic reports (annual and quarterly reports) annually. A periodic report includes, as previously indicated, a narrative summary, individual case safety reports, and history of actions taken. Although some companies may submit 400 periodic reports annually, others only submit 1 periodic report annually.

The comments stated that the burden estimate seems to reflect only FDA's effort and not that of the respondents. The comments said that the hours per response for preparing periodic reports is grossly underestimated. One comment said that the preparation, quality control, and duplication of NDA periodic reports takes, on average, from 16 to 40 hours each, while the other comment said that this processing takes from 100 to 300 hours for each periodic report. The comments said that all adverse experience reports, including the non-15-day alert reports, need to be taken into account when calculating the burden, because all need to be reviewed, assessed, and processed for determination of ''expedited'' status and for inclusion in the periodic safety update reports. For example, the comments said that one company received approximately 49,000 initial adverse drug experience reports in association with their marketed prescription products from worldwide sources in 2001, approximately 4,800 of which qualified as 15-day alert reports; this included both initial and followup reports. Another company received approximately 20,000 initial adverse event reports from worldwide sources in 2001, approximately 2,000 of which qualified as 15-day alert reports; this included both initial and followup reports.

FDA notes that the estimate of 5 hours in the **Federal Register** of February 25, 2002, document was a typographical error. The correct estimate should be 28 hours. As explained in the information collection notice that published in the **Federal Register** of January 29, 1999 (64 FR 4665), this estimate is based on industry suggestions.

The comments questioned whether there are no capital, operating, or maintenance costs associated with maintaining records of adverse experience reports for 10 years. The comments said that companies must maintain facilities to store paper records in addition to backup records on other media. Costs for storage and retrieval vary widely, depending on the volume of records, rental fees, transportation costs, and retrieval fees, but may be substantial (i.e., thousands of dollars annually).

FDA agrees that there are maintenance costs associated with maintaining records of adverse experience reports for 10 years. FDA estimates that these costs are approximately $2,000 per company annually, as suggested by the comments.

The comments also provided several suggestions on how the regulations should be revised to enhance the reporting efficiency and to minimize the burden of the collection of information. For example, the comments said that FDA should revise the requirements to be consistent with the International Conference on Harmonization (ICH) guidelines for periodic safety update reports.

FDA is in the process of revising its safety reporting and recordkeeping regulations and will consider these comments in finalizing its rulemaking. Respondents will have an opportunity to comment further on these rulemaking initiatives. As stated in the **Federal Register** of May 13, 2002 (67 FR 33059), FDA is planning to publish a proposed rule that would amend the expedited and periodic safety reporting regulations

for human drugs and biologics to revise certain definitions and reporting formats as recommended by the ICH and to define new terms; to possibly add to or revise current reporting requirements; to consider revising certain reporting timeframes; and to suggest other revisions to these regulations to enhance the quality of safety reports received by FDA.

Respondents to this collection of information are manufacturers, packers, distributors, and applicants. FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
310.305(c)(5)	1	1	1	1	1
314.80(c)(1)(iii)	5	1	5	1	5
314.80(c)(2)	683	15	10,245	28	286,860
Total					286,866

[1]The reporting burden for §§ 310.305(c)(1), (c)(2), and (c)(3), and 314.80(c)(1)(i) and (c)(1)(ii) was reported under OMB control number 0910–0291. There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
310.305(f)	25	1	25	1	25
314.80(i)	683	1	683	1	683
Total					708

[1]There are no capital costs or operating costs associated with this collection of information. There are maintenance costs of $2,000 annually.

These estimates are based on FDA's knowledge of adverse drug experience reporting, including knowledge about the time needed to prepare the reports and the number of reports submitted to the agency.

Dated: July 15, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–18462 Filed 7–19–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02F–0316]

Intralytix, Inc.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Intralytix, Inc., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of a mixture of bacteriophages as an antimicrobial agent on foods, including fresh meat, meat products, fresh poultry, and poultry products.

FOR FURTHER INFORMATION CONTACT: Raphael A. Davy, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 202–418–3405.

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 2A4738) has been filed by Intralytix, Inc., c/o Lewis & Harrison, 122 C St. NW., suite 740, Washington, DC 20001. The petition proposes to amend the food additive regulations to provide for the safe use of a mixture of bacteriophages as an antimicrobial agent on foods, including fresh meat, meat products, fresh poultry, and poultry products.

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: June 27, 2002.

Alan M. Rulis,

Director, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition.

[FR Doc. 02–18465 Filed 7–19–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer at (301) 443–1891.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques