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

or other forms of information technology.

Proposed Project: Maternal and Child Health Services Title V Block Grant Program—Guidance and Forms for the Title V Application/Annual Report (OMB No. 0915–0172)—Revision

The Health Resources and Services Administration (HRSA) proposes to revise the *Maternal and Child Health Services Title V Block Grant Program—Guidance and Forms for the Application/Annual Report.* The guidance is used annually by the 50 States and 9 jurisdictions in making application for Block Grants under Title V of the Social Security Act and in preparing the required annual report. The proposed revisions follow and build on extensive consultation received from a Workgroup convened in 2002 to provide suggestions for improving the guidance and forms. The proposed revisions are editorial and technical revisions in nature and are based on the experience of the States and jurisdictions using previous versions of the guidance. Changes include consolidating the narrative to reduce redundancy, and reducing the number of Health Status Indicators (HSI) required in the application/annual report.

In addition, HRSA proposes changing the format for electronic submission to direct web entry. Web based data and text entry will provide for automatic calculation of ratios, rates, and percentages, carry data over year-to-year and assure that data used in multiple tables are entered only once. It will also facilitate the orderly printing of tables, text, and required appendices.

The guidance used annually by the 50 States and 9 jurisdictions had a previous estimated burden of 358 hours. Based on the new revisions and more efficient electronic submission, the estimated burden has been reduced by 5% to 322 hours. The estimated response burden is as follows:

Type of form	Number of respondents	Responses per respondent	Burden hours per response	Total burden hours
Application and Annual Report, with needs assessment*:				
States	50	1	428	21,400
Jurisdictions	9	1	228	2,052
Application and Annual Report, without needs assessment*:				
States	50	1	313	15,658
Jurisdictions	9	1	126	1,134

* The Application and Annual Report, with needs assessment, will be submitted in FY 2005. The Application and Annual Report, without needs assessment, will be submitted in FY 2003 and FY 2004. The average annual total burden hours for the next three years is 19,007. The average annual burden per respondent 322 hours.

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 11A–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of notice.

Dated: July 16, 2002.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 02–18323 Filed 7–19–02; 8:45 am]

BILLING CODE 4165–15–P

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 on (301) 443–1129.

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 or other forms of information technology.

Proposed Project: Traumatic Brain Injury (TBI) Grantee Survey—(NEW)

The TBI program is designed to emphasize activities by States to ensure access to comprehensive and coordinated services for individuals with TBI and their families, including: Pre-hospital care; emergency department care; acute hospital care, rehabilitation; transitional services; education and employment; and long-term community support, on a statewide basis. The program provides grants to strengthen infrastructure, improve community supports and services, develop and evaluate model approaches to integrating TBI services into the broader service delivery system, and generate support from local and private sources for sustaining their efforts after the grant's completion.

HRSA is planning to conduct to conduct a survey to assess the degree to which States have implemented the core components of a TBI State Plan, which include: A designated State Health Agency and staff position, a Statewide Advisory Board, a Statewide needs assessment, and a Statewide Action Plan. The results of this assessment will be used to determine funding priorities, including development of appropriate guidelines and provision of technical assistance to States, demonstration grants, information collection and sharing among State agencies, and training programs for health professionals.

HRSA has included national performance measures for TBI in this survey in accordance with the requirements of the ''Government Performance and Results Act (GPRA) of 1993'' (Public Law 103–62). This act requires the establishment of measurable goals for Federal programs that can be reported as part of the budgetary process, thus linking funding decisions with performance.