ART programs regarding the status of the new contract and future years' data collection activities as information becomes available.

FOR FURTHER INFORMATION CONTACT: Victoria Wright, Assisted Reproductive Technology Epidemiology Unit at (770) 488–6370.

Dated: January 29, 2004.

Joseph R. Carter,

Deputy Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 04–2395 Filed 2–4–04; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Grants Application Data Summary Administration for Native Americans Language Application Information.

OMB: No.: New collection.

Description: Grants Application Data Summary (GADS) information is collected as part of a grant application. The GADS provides information used to prepare the legislatively mandated annual report to Congress on the status of American Indians, Native Alaskans, Native Hawaiians and Pacific Islander communities.

The purpose of this information collection is to collect information from applicants that the Administration for Native Americans can use for more accurate reporting to the Administration for Children and Families and to Congress on the status of American Indians, Native Alaskans, Native Hawaiians and Pacific Islander communities. This information collection is conducted in accordance with 42 USC 2991b–2(4) of the Native American Programs Act of 1974, as amended.

Respondents: Tribal governments, native non-profits, tribal colleges & universities.

Annual Burden Estimates:

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Language GADS Form	650	1	28	18,200

Estimated Total Annual Burden Hours: 18,200.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Office. All requests should be identified by the title of the information collection. E-mail address: *rsargis@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Washington, DC, Attn: Desk Officer for ACF, E-mail: *katherine_t._astrich@omb.eop.gov.*

Dated: January 29, 2004.

Robert Sargis,

Reports Clearance, Officer.

[FR Doc. 04–2324 Filed 2–4–04; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Grants Application Data Summary Administration for Native Americans Environmental Application Information.

OMB No.: New collection.

Description: Grants Application Data Summary (GADS) information is collected as part of a grant application. The GADS provides information used to prepare the legislatively mandated annual report to Congress on the status of American Indian and Native Alaskan communities.

This information collected from applicants will allow the Administration for Native Americans to more accurately report to the Administration for Children and Families and to Congress on the status of American Indians and Native Alaskans. This information collection is conducted in accordance with 42 USC 2991b–2(4).

Respondents: Tribal governments, native non-profits, tribal colleges & universities.

Annual Burden Estimates:

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Environmental GADS Form	650	1	28	18,200

Estimated Total Annual Burden Hours: 18,200.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: *rsargis@acf.hhs.gov.* All requests should be identified by the title of the information collection.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, NW., Washington, DC 20503, Attn: Desk

Officer for ACF, E-mail: *katherine_t._astrich@omb.eop.gov.*

Dated: January 29, 2004.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 04–2325 Filed 2–4–04; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1998F–0716]

Dainippon Ink and Chemicals, Inc.; Withdrawal of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a future filing, of a food additive petition (FAP 8B4619) proposing that the food additive regulations be amended to provide for the expanded safe use of a polyester-polyurethane resin-acid dianhydride adhesive in retortable pouches for use in contact with fatty food.

FOR FURTHER INFORMATION CONTACT: Mark Hepp, Center for Food Safety and Applied Nutrition (HFS–275), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3858, 202–418–3098.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of August 31, 1998 (63 FR 46226), FDA announced that a food additive petition (FAP 8B4619) had been filed by Dainippon Ink and Chemicals, Inc., c/o Center for Regulatory Services, 2347 Paddock Lane, Reston, VA 20191. The petition proposed to amend the food additive regulations in § 177.1390 *Laminate structures for use at temperatures of 250 °F and above* (21 CFR 177.1390) to provide for the expanded safe use of a polyester-polyurethane resin-acid dianhydride adhesive in retortable pouches for use in contact with fatty food. Dainippon Ink and Chemicals, Inc., has now withdrawn the petition without prejudice to a future filing (21 CFR 171.7).

Dated: January 9, 2004.

Laura M. Tarantino,

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

[FR Doc. 04–2313 Filed 2–4–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1996D–0041]

International Conference on Harmonisation; Guidance on Addendum to E2C Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled ''Addendum to E2C Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs'' (the ICH E2C guidance). The guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). In the **Federal Register** of May 19, 1997 (62 FR 27470), FDA published the ICH E2C guidance, which recommends a unified standard for the format, content, and reporting frequency for postmarketing periodic safety update reports (PSURs) for drug and biological products. This guidance, an addendum to the ICH E2C guidance, provides additional information on the content and format of PSURs, including clarification of the objectives, general principles, and model for PSURs. This guidance is intended to help harmonize collection and submission of postmarketing clinical safety data.

DATES: You may submit written or electronic comments at any time.

ADDRESSES: Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Submit written requests for single copies of the guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3844, FAX: 888–CBERFAX. Send two self-addressed adhesive labels to assist the office in processing your requests. Requests and comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Min Chen, Center for Drug Evaluation and Research (HFD–430), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3159, or Miles Braun, Center for Biologics Evaluation and Research (HFM–220), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–6090.

Regarding the ICH: Michelle Limoli, Office of International Programs (HFG–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4480.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is