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 Dainippon Ink and Chemicals, Inc., has now withdrawn the petition without prejudice to a future filing (21 CFR 171.7).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

provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, Health Canada, and the European Free Trade Area.

In the **Federal Register** of December 31, 2002 (67 FR 79939), FDA published a notice announcing the availability of a draft tripartite guidance entitled ''Addendum to E2C Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs.'' The notice gave interested persons an opportunity to submit comments by January 24, 2003.

After consideration of the comments received and revisions to the draft guidance, a final draft of the guidance was submitted to the ICH steering committee and endorsed by the three participating regulatory agencies in February 2003.

This guidance provides additional information on the objectives, general principles, and model for PSURs specified in the ICH E2C guidance, including clarification of the following topics:

- When separate PSURs will be considered appropriate,
- Synchronization of National Birthdates with the International Birthdates,
- Reporting frequency and time for submission changes, and
- Use of the reference safety information.

In addition, this guidance includes information on the following topics not previously addressed in the ICH E2C guidance.

- Summary bridging reports and addendum reports,
- Executive summaries, and
- Information on risk management programs and risk-benefit analyses.

The document should be used in conjunction with the ICH E2C guidance.

This guidance represents the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may, at any time, submit to the Division of Dockets Management (see **ADDRESSES**) written comments on the guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/ohrms/dockets/default.htm*, *http://www.fda.gov/cder/guidance/index.htm*, or *http://www.fda.gov/cber/publications.htm*.

Dated: January 23, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–2314 Filed 2–4–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0041]

Draft Guidance for Industry on Providing Regulatory Submissions in Electronic Format—Content of Labeling; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Content of Labeling.'' This draft guidance is one in a series of guidance documents on providing regulatory submissions to the FDA in electronic format. In the **Federal Register** of December 11, 2003 (68 FR 69009), FDA published a final regulation (the electronic labeling rule) requiring that the content of labeling for marketing applications be submitted in electronic format in a form that FDA can process, review, and archive. The draft guidance provides information on submitting the content of labeling in electronic format for review with new drug applications (NDAs), abbreviated new drug applications (ANDAs), and biological license applications (BLAs).

DATES: Submit written comments on the draft guidance by April 5, 2004. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft 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 to 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. Send one self-addressed adhesive label to assist that office in processing your requests. Submit telephone requests to 800–835–4709 or 301–827–1800. Submit written comments on the draft 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*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Randy Levin, Center for Drug Evaluation and Research (HFD–140), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5411, e-mail: *levinr@cder.fda.gov*, or

Robert Yetter, Center for Biologics Evaluation and Research (HFM–25), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0373.

SUPPLEMENTARY INFORMATION:

I. Background

In December 2003, FDA published the electronic labeling regulation, which requires the submission of the content of labeling in electronic format for marketing applications. The requirements of the electronic labeling rule can be found in 21 CFR 314.50(l) for NDAs, 21 CFR 314.94(d) for ANDAs, 21 CFR 601.14(b) for BLAs, and 21 CFR 314.81(b) for annual reports on marketing applications. The regulations specify that the content of labeling must be submitted electronically in a form that FDA can process, review, and archive. The regulations also state that FDA will periodically issue guidance on how to provide the electronic submission.

II. The Draft Guidance

FDA is announcing the availability of a draft guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Content of Labeling.'' The draft guidance provides information on how to submit the content of labeling in electronic format.

In the preambles of the proposed and final rules on electronic labeling, FDA identified portable document format (PDF) as the only type of electronic file format that the agency has the ability to