and Drug Administration, 5630 Fishers Lane, rm. 1060, Rockville, MD 20852. Two copies of any comments are to be submitted, except that individuals may submit one copy. Received comments may be reviewed at the FDA Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Submit one original and two copies of written comments to FSIS Docket Clerk, Docket No. 00–048N, U.S. Department of Agriculture, Food Safety and Inspection Service, rm. 102, Cotton Annex, 300 12th St, SW., Washington, DC 20250–3700. All comments submitted in response to this notice will be available for public inspection in the Docket Clerk's office between 8:30 a.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT:

For information concerning the draft risk assessment document: Sherri B. Dennis, Risk Assessment Coordinator, Center for Food Safety and Applied Nutrition (HFS–032), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–260–3984, FAX 202–260–9653, e-mail: sdennis@cfsan.fda.gov.

For information concerning the risk management action plan: Kathy Gombas, Center for Food Safety and Applied Nutrition (HFS–615), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4231, FAX 202–260–0136, e-mail: kgombas@cfsan.fda.gov or Charles Edwards, Food Safety and Inspection Service, U.S. Department of Agriculture, rm. 405, Cotton Annex, 300 12th St. SW., Washington, DC 20250–3700, 202–205–0675, FAX 202–205–0080.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 19, 2001 (66 FR 5515), the Department of Health and Human Services and USDA announced the availability of two documents: A draft risk assessment on the relationship between foodborne *L. monocytogenes* and human health and a draft risk management action plan. Comments were sought on the technical aspects of the draft risk assessment in the following areas: (1) The assumptions made, (2) the modeling technique, (3) the data used, and (4) the transparency of the draft risk assessment document. The agencies also invited comments on the risk management strategies as presented in the draft action plan. Interested persons were given until March 20, 2001, to comment on the draft risk assessment and draft action plan. FDA and USDA/FSIS extended the comment period to May 21, 2001 (66 FR 13545, March 6, 2001), in response to the requests of the National Food Processors Association and the LM Working Group and because a public meeting to receive comments on these documents was scheduled on March 19, 2001, only 1 day before the close of the comment period. The LM Working Group has requested a second extension of the comment period in part to allow time to: (1) Collect and review new data, and (2) evaluate the model and the appropriateness of the new data to improve the assessment. In response, FDA and USDA/FSIS are extending the comment period to July 18, 2001; however, the agencies do not anticipate further extensions of the comment period for these draft documents.

To be considered, submit written comments to FDA Dockets Management Branch or the FSIS Dockets Clerk (addresses above) by July 18, 2001.

Printed copies of the draft risk assessment and the risk management action plan and/or a CD–ROM of the risk assessment model may be requested by faxing your name and mailing address with the names of the documents you are requesting to the CFSAN Outreach and Information Center at 1–877–366–3322. The documents may be reviewed at the FDA Dockets Management Branch or the FSIS Docket Clerk's Office at the addresses and hours noted above. The draft risk assessment and action plan documents are also available electronically as follows: www.cfsan.fda.gov, www.fsis.usda.gov, www.foodsafety.gov.

Dated: May 18, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–13055 Filed 5–18–01; 2:59 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–4071]

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH); Final Guidance for Industry on ''Impurities: Residual Solvents in New Veterinary Medicinal Products, Active Substances and Excipients'' (VICH GL18); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a final guidance for industry (#100) entitled ''Impurities: Residual Solvents in New Veterinary Medicinal Products, Active Substances and Excipients'' (VICH GL18). This guidance has been adapted for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) from a similarly titled guidance regarding pharmaceuticals for human use, which was adopted by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The guidance is intended to recommend acceptable amounts of residual solvents in new animal drugs (referred to as pharmaceuticals or veterinary medicinal products in the final guidance) for the safety of the target animal as well as for the safety of human consumers of products derived from treated food producing animals. It is intended to assist in developing new animal drug applications (referred to as marketing applications in the final guidance) submitted to the European Union, Japan, and the United States.

DATES: You may submit written comments at any time.

ADDRESSES: You may submit written requests for a single copy of the final guidance entitled ''Impurities: Residual Solvents in New Veterinary Medicinal Products, Active Substances and Excipients'' (VICH GL18) to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

You may submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kevin J. Greenlees (HFV–150), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6977, e-mail, kgreenle@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote the international harmonization of regulatory requirements. FDA has

participated in efforts to enhance harmonization and has expressed its commitment to seek scientifically based harmonized technical requirements for the development of pharmaceutical products. One of the goals of harmonization is to identify and then reduce the differences in technical requirements for drug development among regulatory agencies in different countries.

FDA has actively participated in the ICH for several years to develop harmonized technical requirements for the approval of human pharmaceutical and biological products among the European Union, Japan, and the United States. The VICH is a parallel initiative for veterinary medicinal products. The VICH is concerned with developing harmonized technical requirements for the approval of veterinary medicinal products in the European Union, Japan, and the United States, and includes input from both regulatory and industry representatives.

The VICH Steering Committee is composed of member representatives from the: European Commission; European Medicines Evaluation Agency; European Federation of Animal Health; the U.S. FDA; the U.S. Department of Agriculture; the Animal Health Institute; the Japanese Veterinary Pharmaceutical Association; the Japanese Association of Veterinary Biologics; and the Japanese Ministry of Agriculture, Forestry and Fisheries.

Two observers are eligible to participate in the VICH Steering Committee: One representative from the Government of Australia/New Zealand, and one representative from the industry in Australia/New Zealand. The VICH Secretariat, which coordinates the preparation of documentation, is provided by the Confédération Mondiale de L'Industrie de la Santé Animale (COMISA). A COMISA representative also participates in the VICH Steering Committee meetings.

II. Guidance on Impurities: Residual Solvents

In the **Federal Register** of October 12, 1999 (64 FR 55296), FDA published the notice of availability of the draft guidance entitled ''Impurities: Residual Solvents'' (VICH GL18) giving interested persons until November 12, 1999, to submit comments. FDA received no comments. The final guidance was submitted to the VICH Steering Committee. At a meeting held on June 14 through 16, 2000, the VICH Steering Committee endorsed the final guidance for industry, VICH GL18.

This guidance is intended to recommend acceptable amounts of residual solvents in new animal drugs (referred to as pharmaceuticals or veterinary medicinal products in the final guidance) for the safety of the target animal as well as for the safety of human consumers of products derived from treated food-producing animals. The guidance is intended to assist in developing new animal drug applications (referred to as marketing applications in the final guidance) submitted to the European Union, Japan, and the United States.

This final level 1 guidance is being issued consistent with FDA's good guidance practices regulation (65 FR 56468, September 19, 2000). 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 applicable statutes and regulations. Information collected is covered under OMB control number 0910–0032.

III. Electronic Access

Persons with access to the Internet may obtain the document at http://www.fda.gov/cvm.

IV. Comments

As with all of FDA's guidances, the public is encouraged to submit written comments with new data or other new information pertinent to this guidance. FDA will periodically review the comments in the docket and, where appropriate, will amend the guidance. The agency will notify the public of any such amendments through a notice in the **Federal Register**.

Interested persons may, at any time, submit written or electronic comments regarding this guidance. Written comments should be submitted to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. Comments may also be submitted electronically on the Internet at http://www.fda.gov/dockets/ecomments. Once on this Internet site, select ''99D–4071 Impurities: Residual Solvents in New Veterinary Medicinal Products'' and follow the directions.

Dated: May 11, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–12770 Filed 5–21–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–2125–N]

Medicaid Program; Infrastructure Grant Program To Support the Design and Delivery of Long Term Services and Supports That Permit People of Any Age Who Have a Disability or Long-Term Illness To Live in the Community

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice of funding availability.

SUMMARY: This notice announces the availability of approximately $70 million in grant funding through ''Systems Change Grants for Community Living''. The ''Systems Change'' grants include four distinct competitive grant opportunities: (1) ''Nursing Facility Transitions''; (2) ''Community-Integrated Personal Assistance Services and Supports''; (3) ''Real Choice Systems Change''; and (4) ''National Technical Assistance Exchange for Community Living''. The four grants are designed to assist States to develop enduring infrastructures that support people of any age who have a disability or long-term illness to live and participate in their communities. Applicants include States, State instrumentalities, and other eligible entities as further described in the notice. This notice also contains information about the application process.

DATES: *Deadline for Letter of Intent To Apply:* Applicants should submit a letter of intent to apply for a grant no later than June 8, 2001. Although it is not mandatory for an applicant to submit a letter of intent, we would appreciate receiving a letter of intent from each applicant because it will help us to plan our review panels.

Deadlines for Submission of Grant Applications: To be considered under the Fiscal Year 2001 funding cycle, grant applications must be submitted by the deadlines listed below: