displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0570. The approval expires on December 31, 2008. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: January 3, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–94 Filed 1–9–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1999D–2145] (formerly 99D–2145)

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products; Draft Revised Guidance for Industry on Impurities in New Veterinary Medicinal Products (Revised); Request for Comments; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability for comments of a draft revised guidance for industry (#93) entitled ''Impurities in New Veterinary Medicinal Products (Revised)'' VICH GL11(R). This draft revised guidance, which updates a final guidance on the same topic for which a notice of availability was published in the **Federal Register** of July 7, 2000 (the 2000 guidance), has been developed for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This draft revised document is intended to assist in developing registration applications for approval of veterinary medicinal products submitted to the European Union, Japan, and the United States. The revised guidance addresses only those impurities in new veterinary medicinal drug products classified as degradation products.

DATES: Submit written or electronic comments by February 9, 2006, to ensure their adequate consideration in preparation of the final guidance document. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine (CVM), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855.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 draft revised guidance document.

Submit written comments on the draft revised guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Comments should be identified with the full title of the draft revised guidance and the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Dennis Bensley, Center for Veterinary Medicine (HFV–143), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6956, e-mail: *dbensley@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 procedures for the development of pharmaceutical products. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies in different countries.

FDA has actively participated in the International Conference on Harmonization of Technical Requirements for Approval of Pharmaceuticals for Human Use 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. VICH is a parallel initiative for veterinary medicinal products. 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; Committee on Veterinary Medicinal Products; 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.

Four observers are eligible to participate in the VICH steering committee as follows: One representative from the government of Australia/New Zealand, one representative from the industry in Australia/New Zealand, one representative from the government of Canada, and one representative from the industry of Canada. The VICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation for Animal Health (IFAH). An IFAH representative also participates in the VICH steering committee meetings.

II. Draft Revised Guidance on Impurities in New Veterinary Medicinal Products

In May 2005, the VICH steering committee agreed that a draft revised guidance entitled ''Impurities in New Veterinary Medicinal Products (Revised)'' VICH GL11(R) should be made available for public comment. The draft revised guidance is a revision of a final guidance on the same topic for which a notice of availability was published in the **Federal Register** of July 7, 2000 (65 FR 42019). The draft revised guidance clarifies the 2000 guidance, adds information, and provides consistency with more recently published VICH guidances. The draft revised guidance is a product of the Quality Expert Working Group of VICH. Comments about this draft will be considered by FDA and the Quality Expert Working Group.

This draft revised document is intended to provide guidance for new animal drug applications on the content and qualification of impurities in new veterinary drug substances intended to be used for new veterinary medicinal products, produced by chemical syntheses and not previously registered in a country, region, or member state.

The draft guidance has been revised to add information to certain sections and to provide clarification to other sections of the previous guidance. The

revisions include changes in the following ways: (1) The text on the recommended reporting, identification, and qualification thresholds; (2) the recommended deletion of the exception to conventional rounding practice; (3) modification of the decision tree in Attachment 2, which sets out a recommended approach to identifying and qualifying degradation products; and (4) additions and revisions to the previous glossary including definitions for the terms ''unspecified degradation product,'' ''reporting threshold,'' and ''identification threshold.''

In addition, the guidance was updated to reference, where appropriate, other more recently published VICH guidances relevant to this topic. Finally, minor editorial changes were made to improve the clarity and consistency of the document.

III. Paperwork Reduction Act of 1995

This draft revised guidance contains information collection previsions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in this draft revised guidance have been approved under OMB control number 0910–0032.

IV. Significance of Guidance

This draft revised document, developed under the VICH process, has been revised to conform to FDA's good guidance practices regulation (21 CFR 10.115). For example, the document has been designated ''guidance'' rather than ''guideline.'' In addition, guidance documents must not include mandatory language such as ''shall,'' ''must,'' ''require,'' or ''requirement,'' unless FDA is using these words to describe a statutory or regulatory requirement.

The draft revised VICH guidance (#93) represents the agency's current thinking on impurities in new veterinary drug medicinal products. This draft revised guidance does not create or confer any rights for or on any person and will not operate to bind FDA or the public. An alternative method may be used as long as it satisfies the requirements of applicable statutes and regulations.

V. Comments

This draft revised guidance document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this draft revised guidance document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the draft revised guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

VI. Electronic Access

Electronic comments may also be submitted on the Internet at *http://www.fda.gov/dockets/ecomments*. Once on this Internet site, select Docket No. 1999D–2245, entitled ''Draft Revised Guidance for Industry on Impurities in New Veterinary Medicinal Products (Revised)'' (VICH GL11(R)) and follow the directions.

Copies of the draft guidance document entitled ''Draft Revised Guidance for Industry on Impurities in New Veterinary Medicinal Products (Revised)'' VICH GL11(R) may be obtained on the Internet from the CVM home page at *http://www.fda.gov/cvm*.

Dated: December 30, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–90 Filed 1–9–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7057; fax: 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Polysaccharide Derived Nitric Oxide Releasing Carbon Bound Diazeniumdiolates

Joseph A. Hrabie et al. (NCI)

U.S. Provisional Application No. 60/731,946 filed 31 Oct 2005 (HHS Reference No. E–279–20050–US–01)

Licensing Contact: John Stansberry; 301/435–5236; *stansbej@mail.nih.gov*

The invention discloses a method for producing nitric oxide(NO)-releasing derivatives of any material containing a reducing sugar component. It may be used to produce NO-releasing cotton bandages or surgical fabrics, cellulose filters or dialysis membranes, and drug formulating/compounding agents to prevent stomach irritation. The method involves incorporation of a diazeniumdiolate ($-N_2O_2$) group at one or more carbons via the base-catalyzed replacement of acidic hydrogens and is thus compatible with traditional polysaccharide processing techniques. Monosaccharides such as glucose may also be derivatized.

In addition to licensing, the technology is available for further development through collaborative research opportunities with the inventors.

Hydropneumatic Fluid Control for a Cell Culturing System

Alexandr Chanturiya, Svetlana Glushakova, and Joshua Zimmerberg (NICHD)

U.S. Provisional Application No. 60/725,327 filed 12 Oct 2005 (HHS Reference No. E–166–2005/0–US–01)

Licensing Contact: Michael Shmilovich; 301/435–5019; *shmilovm@mail.nih.gov*

Available for licensing and commercial development is a hydropneumatic fluid control system in which cell culture media is perfused through a bioreactor by gas pressure where the direction of the gas directs the direction of perfusion. The gas can also act to regulate the pH of the cell culture media. Containers holding the cell culture media are situated on either side of an axis of rotation of a platform. The weight of the container as it fills with media forces the platform to oscillate. The oscillation actuates a piston—also coupled to the platform—which regulates a valve that switches the flow of gas to the other container. This system does not use electricity and, with an appropriate gas mixture, saturates cell culture media with gas.

In addition to licensing, the technology is available for further