

better comply with labeling requirements, especially in light of growing concerns about obesity and food allergens. Information presented will be based on agency position as articulated through regulation, compliance policy guides, and information previously made available to the public. Topics to be discussed at the workshop include: (1) Mandatory label elements, (2) nutrition labeling requirements, (3) health and nutrition claims, (4) the Food Allergen Labeling and Consumer Protection Act of 2004, and (5) special labeling issues such as exemptions. FDA expects that participation in this public workshop will provide regulated industry with greater understanding of the regulatory and policy perspectives on food labeling and increase voluntary compliance.

Dated: December 27, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E5-8225 Filed 1-3-06; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2004D-0468]

#### Guidance for Industry on Development of Target Animal Safety and Effectiveness Data to Support Approval of Non-Steroidal Anti-Inflammatory Drugs for Use in Animals; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry (#123) entitled "Development of Target Animal Safety and Effectiveness Data to Support Approval of Non-Steroidal Anti-Inflammatory Drugs for Use in Animals." This guidance provides recommendations regarding the development of target animal safety and effectiveness data to support approval of veterinary non-steroidal anti-inflammatory drugs (NSAIDs), specifically cyclooxygenase (COX) inhibitors.

**DATES:** Submit written or electronic comments on agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine, 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 guidance document.

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>. Comments should be identified with the full title of the guidance and the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:**

Linda Wilmot, Center for Veterinary Medicine (HFV-114), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0135, e-mail: [lwilmot@cvm.fda.gov](mailto:lwilmot@cvm.fda.gov).

**SUPPLEMENTARY INFORMATION:**

#### I. Background

In the **Federal Register** of November 10, 2004 (69 FR 65202), FDA published a notice of availability for a draft guidance entitled "Development of Target Animal Safety and Effectiveness Data to Support Approval of Non-Steroidal Anti-Inflammatory Drugs for Use in Animals" giving interested persons until January 24, 2005, to comment on the draft guidance. This final guidance reflects changes in response to comments received on the draft guidance. In addition, FDA provided further clarification regarding recommendations on the generation of pharmacokinetic (PK) data. In particular, FDA included several examples of the type of PK information that would be recommended for certain types of products including those involving repeated administration or multiple dosage forms.

#### II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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 addressed in this guidance have been approved under OMB control number 0910-0032.

#### III. Significance of Guidance

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance represents the agency's current thinking on the development of target animal safety and effectiveness

data to support approval of non-steroidal anti-inflammatory drugs for use in animals. 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.

#### IV. Comments

As with all FDA guidances, the public is encouraged to submit written or electronic comments with new data or other new information pertinent to this guidance. FDA periodically will 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 submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this 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 should be identified with the docket number found in brackets in the heading of this document. A copy of the guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

#### V. Electronic Access

Persons with access to the Internet may obtain the guidance at either <http://www.fda.gov/cvm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: December 21, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E5-8223 Filed 1-3-06; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2004D-0493]

#### Guidance for Industry and Review Staff on Recommended Approaches to Integration of Genetic Toxicology Study Results; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry

and review staff entitled "Recommended Approaches to Integration of Genetic Toxicology Study Results." This guidance is intended to inform industry and the review staff in the Center for Drug Evaluation and Research (CDER) on how CDER views positive findings in genetic toxicology assays during drug development. The guidance provides recommendations on how to proceed with clinical studies while ensuring the safety of study participants when results in genotoxicity studies suggest a potential cancer or genetic hazard.

**DATES:** Submit written or electronic comments on agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of this 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. Send one self-addressed adhesive label to assist that office in processing your requests. 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>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** David Jacobson-Kram, Center for Drug Evaluation and Research (6411), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6488, Silver Spring, MD 20993, 301-796-0175.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of a guidance for industry and review staff entitled "Recommended Approaches to Integration of Genetic Toxicology Study Results." Pharmaceuticals administered through oral, intravenous, topical, and other routes, as appropriate, are subject to this guidance.

In the **Federal Register** of December 2, 2004 (69 FR 70153), FDA announced the availability of a draft version of the guidance entitled "Recommended Approaches to Integration of Genetic Toxicology Study Results." When the draft guidance was published, FDA requested comments on the document. Some changes were made to the draft document based on comments submitted to the docket including the following changes: (1) The guidance

now suggests that for a compound giving positive results in a genetic toxicology assay, an alternative to demonstrating "mechanism of action" would be ruling out mechanisms involving direct interaction with deoxyribonucleic acid (DNA) and (2) alkaline elution is included as an example of an assay for measuring DNA damage. Other editorial changes were also made.

A number of comments to the docket suggested that the fourth test in the International Conference on Harmonisation (ICH) battery should be an option for compounds giving a positive response in one of the initial assays. This change was not included. Positive responses are primarily seen in the *in vitro* chromosomal aberration assay and/or the mouse lymphoma assay. Because these two tests measure common genetic lesions and have similar drug exposure protocols, the data from the two assays can be used to corroborate results.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on recommended approaches to integration of genetic toxicology study results. 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 submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the guidance at any time. 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. 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 either <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: December 21, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

[Docket No. 1999D-2215] (formerly 99D-2215)

#### **International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products; Draft Revised Guidance for Industry on Impurities in New Veterinary Drug Substances (Revision); 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 (#92) entitled "Impurities in New Veterinary Drug Substances (Revision)" VICH GL10(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). The draft revised document is intended to provide guidance for registration applicants on the content and qualification of impurities in new veterinary drug substances produced by chemical syntheses and not previously registered in a country, region, or member state.

**DATES:** Submit written or electronic comments by February 3, 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 request. 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, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.