

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D-0468]

D.D.M.
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Certifier L. C. ANDERSON

Draft Guidance for Industry on Development of Target Animal Safety and Effectiveness Data to Support Approval of Non-Steroidal Anti-Inflammatory Drugs for Use in Animals;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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance for industry (#123) entitled “Development of Target Animal Safety and Effectiveness Data to Support Approval of Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) for Use in Animals.” This draft guidance is intended to provide specific advice regarding the development of target animal safety and effectiveness data to support approval of veterinary NSAIDs, specifically cyclooxygenase (COX) inhibitors.

DATES: Submit written or electronic comments on agency guidances by *[insert date 75 days after publication in the **Federal Register**]* to ensure their adequate consideration in preparation of the final document. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance document to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855.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

Submit written comments on the draft guidance document to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 Comments should be identified with the full title of the draft guidance document and the docket number found in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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: Iwilmot@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

This draft guidance document provides information on approaches to the development of target animal safety and effectiveness data to support approval of veterinary NSAIDs—specifically, NSAIDs that reduce the production of prostaglandins by inhibiting the COX pathway. NSAIDs that inhibit lipooxygenase, or both lipooxygenase and COX, or act as cytokine antagonists. The Center for Veterinary Medicine (CVM) may recommend alternative product development strategies to complete its evaluation.

11. Significance of Guidance

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft 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. The document does not create or confer any rights for or on any person and will not operate to bind FDA or the public. Alternative

methods may be used as long as they satisfy the requirements of the applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

The collection of information requirements are approved by the Office of Management and Budget (OMB) under OMB control number 0910-0032.

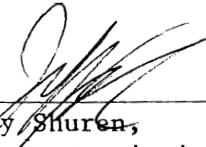
IV. Comments

This draft guidance document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit written or electronic comments to the Division of Dockets Management (see **ADDRESSES**) regarding this draft guidance document. Two paper copies of any mailed comments are to be submitted, 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 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

Electronic comments may be submitted on the Internet at *http://www.fda.gov/dockets/ecomments*. Once on this site, select [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 (NSAIDs) for use in Animals” and follow the directions. Copies of this draft guidance may be obtained on the Internet from the CVM home page at *http://www.fda.gov/cvm*.

Dated: 11/2/04
November 2, 2004:



Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 04-????? Filed ??-??-04;8:45 am]

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