

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D-0340]

DDM

Request Date	9-16-05
Publication Date	9-19-05
Comments	A. Corbin

Draft Guidance for Industry on Acne Vulgaris: Developing Drugs for Treatment; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “Acne Vulgaris: Developing Drugs for Treatment.” This document has been developed to provide guidance on the development of drug products for the treatment of acne vulgaris other than nodulocystic acne.

DATES: Submit written or electronic comments on the draft guidance by *[insert date 90 days after date of publication in the Federal Register]*. 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ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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: Frank Cross, Center for Drug Evaluation and Research (HFD-540), Food and Drug Administration, 9201 Corporate Blvd., Rockville, MD 20850, 301-827-2020.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Acne Vulgaris: Developing Drugs for Treatment.” This document has been developed to provide guidance on the development of drug products for the treatment of acne vulgaris other than nodulocystic acne. The information presented may help applicants plan clinical studies, design clinical protocols, implement and appropriately monitor the conduct of clinical trials, collect relevant data for analysis, and perform appropriate types of analyses of study data.

The recommendations in the draft guidance are based on careful assessment of important issues raised in the review of clinical trials for acne vulgaris. These recommendations represent the agency’s current thinking regarding design of clinical trials intended to support the approval of drug products for the treatment of acne vulgaris. Applicants are encouraged to discuss development plans with the agency review division before embarking on a study, to ensure that the clinical trial design and analysis plan meet defined objectives.

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent 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

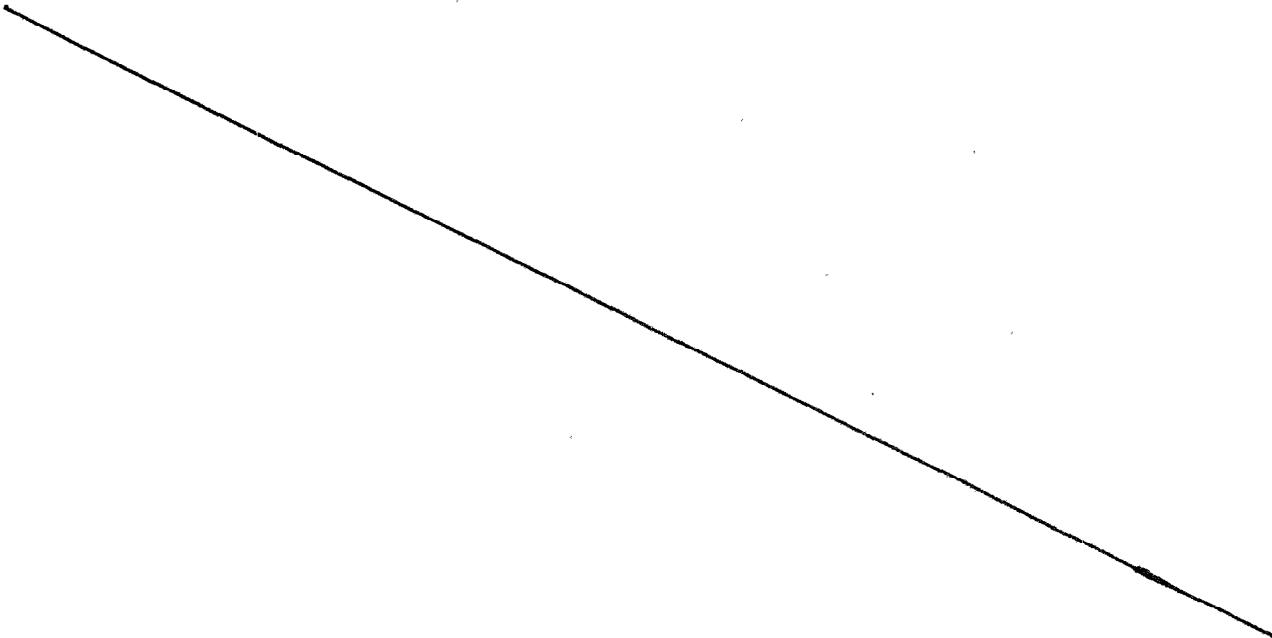
the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance contains information collection provisions 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 collection of information in this guidance has been approved under OMB control number 0910–0001 (expires May 31, 2008).

III. Comments

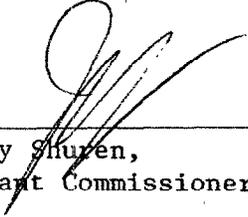
Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.



IV. 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: 9/8/05
September 8, 2005.



Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 05-????? Filed ??-??-05; 8:45 am]

BILLING CODE 4160-01-S

