

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D-0431]

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Certifier R. VEDESMA

DDW

Draft Guidance for Industry and the Food and Drug Administration; Current Good Manufacturing Practices for Combination Products; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Current Good Manufacturing Practices for Combination Products." Once finalized, this guidance will provide guidance to industry and FDA staff on the applicability of current good manufacturing practices (CGMP) for combination products.

DATES: Submit written or electronic comments on the draft guidance by [*insert date 60 days after date of publication in the Federal Register*].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ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Combination Products (HFG-3), 15800 Crabbs Branch Way, suite 200, Rockville, MD 20855. 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 Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.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: Patricia Y. Love, Office of Combination Products (HFG-3), Food and Drug Administration, 15800 Crabbs Branch Way, suite 200, Rockville, MD 20855, 301-427-1934, FAX 301-427-1935, e-mail: *patricia.love@oc.fda.gov*.

SUPPLEMENTARY INFORMATION:

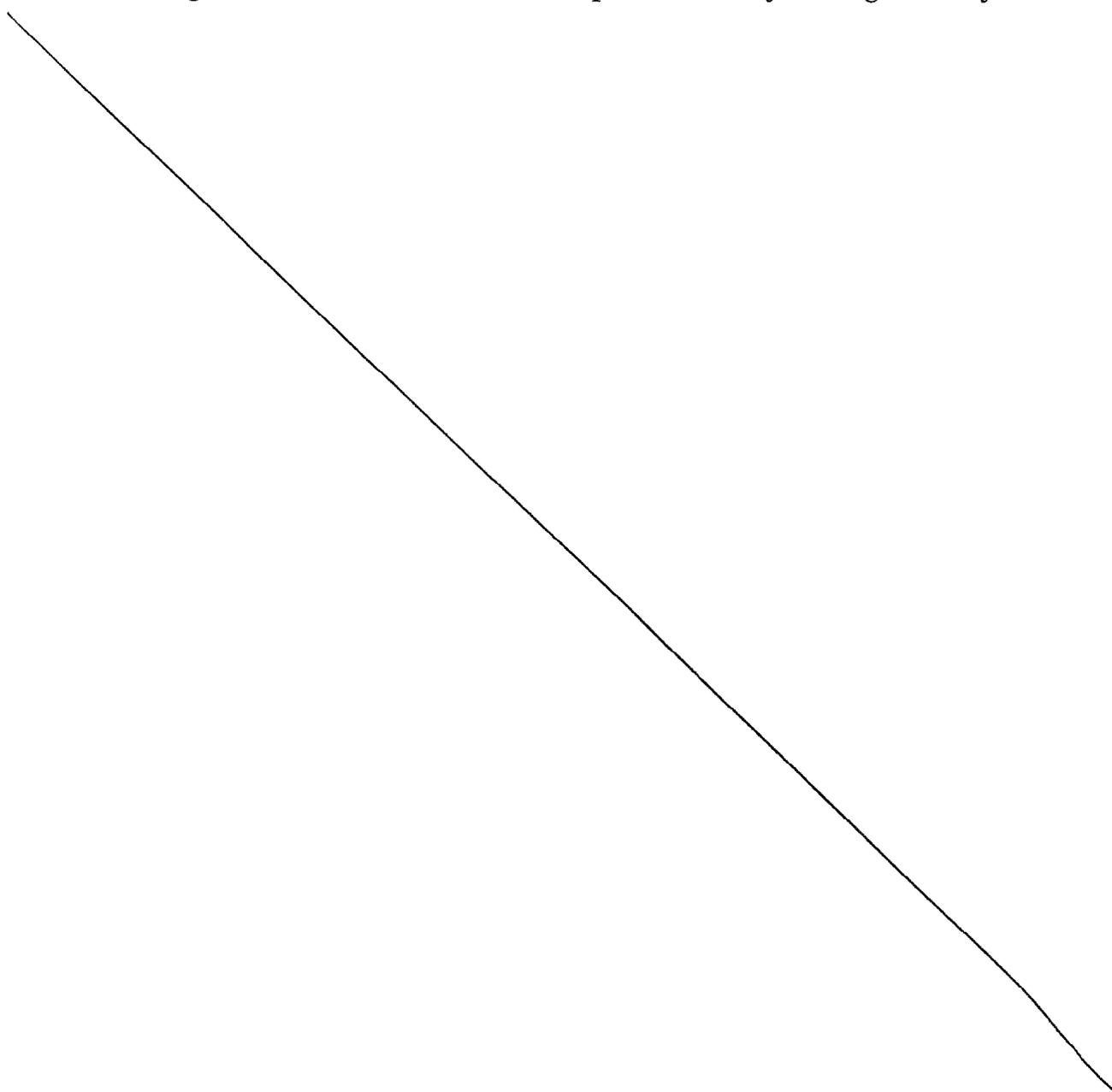
I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Current Good Manufacturing Practices for Combination Products.” Combination products are defined under 21 CFR 3.2(e). This draft guidance document makes recommendations for achieving compliance with applicable CGMPs for the drug, device, or biological product constituent parts of a combination product. In addition, the draft guidance document makes recommendations for achieving compliance with applicable CGMPs for combination products where the constituent parts of a combination product are joined together. The applicable regulations include the CGMP regulations for finished pharmaceuticals, or drug products, and most biological products (21 CFR parts 210 and 211); the biological product regulations for biological products (21 CFR parts 600–680); and the quality system regulations for devices (21 CFR part 820).

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 CGMP for combination products. 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

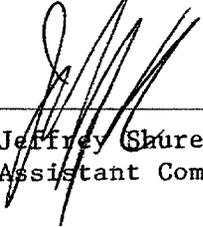
Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Two paper copies of mailed comments are to be submitted, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. 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.



III. Electronic Access

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

Dated: 9/28/04
September 28, 2004.



Jeffrey Skuren,
Assistant Commissioner for Policy.

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

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