

Dated: December 9, 2010.

Leslie Kux,

Acting Assistant, Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-D-0616]

Draft Guidance for Industry on Codevelopment of Two or More Unmarketed Investigational Drugs for Use in Combination; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Codevelopment of Two or More Unmarketed Investigational Drugs for Use in Combination." This guidance is intended to assist sponsors in the codevelopment of two or more novel (not previously marketed) drugs to be used in combination to treat a disease or condition. This guidance provides recommendations and advice on how to address certain scientific and regulatory issues that will arise during codevelopment. The guidance is not intended to apply to development of fixed-dose combinations of already marketed drugs or to development of a single new investigational drug to be used in combination with an approved drug or drugs. The guidance is also not intended to apply to vaccines, gene or cellular therapies, blood products, or medical devices.

DATES: Although you can comment on any guidance at any time (*see* 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by February 14, 2011.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002. 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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Colleen Locicero, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm 4216, Silver Spring, MD 20993-0002, 301-796-1114.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Codevelopment of Two or More Unmarketed Investigational Drugs for Use in Combination." The guidance is intended to assist sponsors interested in developing two or more novel (not previously marketed) drugs to be used in combination. Recent scientific advances have increased our understanding of the pathophysiological processes that underlie many complex diseases, such as cancer, cardiovascular disease, and infectious diseases. This increased understanding has provided further impetus for new therapeutic approaches that rely primarily or exclusively on combinations of drugs directed at multiple therapeutic targets to improve treatment response and minimize development of resistance. In settings in which combination therapy provides significant therapeutic advantages, there is growing interest in the development of combinations of investigational drugs not previously developed for any purpose.

Because the existing developmental and regulatory paradigm focuses primarily on assessment of the effectiveness and safety of a single new investigational drug acting alone, or in combination with an approved drug, FDA believes guidance is needed to assist sponsors in the codevelopment of two or more unmarketed drugs. This guidance is intended to describe a high-level, generally applicable approach to codevelopment of two or more unmarketed drugs. It describes the criteria for determining when codevelopment is an appropriate option, makes recommendations about nonclinical and clinical development strategies, and addresses certain regulatory process issues. The guidance does not apply to vaccines, gene or cellular therapies, or blood products.

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 companion diagnostic devices. 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*) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. 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/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: December 9, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0618]

Statement of Organization, Functions and Delegations of Authority

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has reorganized its Center for Tobacco Products (CTP) by establishing two new offices: Office of Health Communication and Education and the Office of Compliance and Enforcement. In addition, CTP has made improvements to the current offices' functional statements. This organizational change is intended to fill the gaps in the current CTP structure and clarify major responsibilities designed for long-term success in administering the Family Smoking Prevention and Tobacco Control Act.