

Alice E. Till, Ph.D.
VICE PRESIDENT
SCIENCE POLICY AND TECHNICAL AFFAIRS



2006 JUL -6 10:31

June 30, 2004

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Definition of Primary Mode of Action of a Combination Product [Docket No. 2004N-0194, 69 *Federal Register* 25527 (May 7, 2004)]

Dear Madam/Sir:

The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, healthier and more productive lives. Investing more than \$30 billion annually in discovering and developing new medicines, PhRMA companies are leading the way in the search for cures.

The members of the PhRMA fully support the implementation of the Food and Drug Administration's (FDA's) Office of Combination Products (OCP) and the activities that the office is undertaking to clarify the regulation of combination products. We appreciate the opportunity to provide comments to the proposed rule "Definition of Primary Mode of Action of a Combination Product."

In general, we find the proposed rule acceptable. It appears to codify the definition that has been in use and provides a strategy for products where the primary mode of action is not immediately evident or is complex.

However, the document could be improved with more detail and more specific examples to provide clarity and consistency in interpretation. This would assist companies in understanding the thought process for applying the Primary Mode of Action definition and the Assignment Algorithm. For example, a clearer definition of "the agency component with the most experience" would be helpful.

We would like confirmation that the OCP will continue to assist in the review of biologic /drug combination products even when the biologic component of the combination is reviewed by the Center for Drug Evaluation and Research (CDER). With the recent transfer of many biologic products to CDER, we are concerned that the OCP will not feel

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Pharmaceutical Research and Manufacturers of America

Docket No. 2004N-0194

PhRMA Comments

June 30, 2004

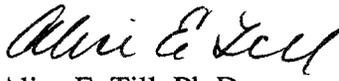
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that these combinations fall within their jurisdiction. We agree that this office does not need to be involved in the review of drug / drug combination products.

Additionally, it would be helpful to note in this rulemaking that the review timeline for drug-device, drug-biologic, and biologic-device combinations be consistent with the performance goals (under the Prescription Drug User Fee Act or the Medical Device User Fee and Modernization Act) of the primary review Center. This is an important result of the primary review determination described in this document.

Thank you for considering these comments as you finalize this rule. Please contact me if you have any questions.

Sincerely,

A handwritten signature in cursive script that reads "Alice E. Till".

Alice E. Till, Ph.D.

CC L. Hayes