illness or provide symptomatic relief, a showing of effectiveness is usually based on a clinical trial comparing the product to a placebo. Such a showing does not necessarily involve a comparison to another active treatment or a product that is known to be effective.

In certain circumstances, however, it may be important to consider whether a new product is less effective than available alternative therapies, when less effectiveness could present a danger to the patient or to the public. For example, it is essential for public health protection that a new therapy be as effective as alternatives that are already approved for marketing when: (1) The disease to be treated is life-threatening or capable of causing irreversible morbidity (e.g., stroke or heart attack); or (2) the disease to be treated is a contagious illness that poses serious consequences to the health of others (e.g., sexually transmitted diseases).

It should be noted that new products are often developed for particular subpopulations who either do not respond to or are not able to tolerate an existing approved therapy. FDA will generally approve for use in such a subpopulation a product that is shown to have effectiveness in this group, regardless of whether the product can be shown to be as effective in the broad target population as the alternative therapy. This is because, in effect, there is no available alternative therapy for the subpopulation. For example, a number of patients cannot tolerate a widely used therapy for an acquired immune deficiency syndrome (AIDS)-related pneumonia. FDA approved atovaquone for use in these patients even though the drug had been shown to be less effective than the standard therapy when tested in a broad population.

An additional issue related to product effectiveness concerns the assertion, by some industry officials, that the act not be interpreted as requiring multiple clinical studies when one ''pivotal'' study could suffice.

FDA believes good science dictates that a showing of effectiveness must be methodologically sound and provide a high level of confidence in the validity of the result. For human drug products, this ordinarily is achieved by independently replicating the result in a second study, to constitute an adequate demonstration of effectiveness for a new product. While a second study may well be needed to replicate results demonstrated in a first study, in some instances, it is possible to replicate results within one large, well-designed, multi-center study. FDA emphasizes that this approach can be successful only when results are strong. The agency has, in the past, approved new human drug products on the basis of a single, multi-center study. Examples include dornase alfa for the treatment of cystic fibrosis, timolol for treatment of people after a heart attack, and zidovudine for AIDS. A statistically marginal result, even in a very large study, cannot provide convincing evidence without replication.

For medical devices, where the mechanism of action is a result of product design and substantially verified by in vitro performance testing, the agency has routinely relied on single studies evaluated for internal and across-center consistency to provide this high level of confidence in the result.

Dated: July 27, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

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Statement of Organization, Functions, and Delegations of Authority

Part H, Chapter HF (Food and Drug Administration) of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (35 FR 3685, February 25, 1970, and 56 FR 29484, June 27, 1991, as amended most recently in pertinent part at 58 FR 14214, March 16, 1993) is amended to reflect the following reorganization in the Food and Drug Administration (FDA).

The Office of the Center Director (OCD), Center for Drug Evaluation and Research (CDER) is being reorganized to enhance CDER's responsiveness to its internal and external customers. The Executive Operations Staff is being established to combine project management, executive secretariat, and program management functions. The functions and staff of the Division of Regulatory Affairs are being transferred from the Office of Compliance to OCD as the Regulatory Affairs Staff.

Under section HF–B, Organization:

1. Delete the subparagraph *Office of the Center Director (HFN1)* under the *Center for Drug Evaluation and Research (HFN),* in its entirety and insert a new subparagraph reading as follows:

Office of the Center Director (HFN1). Promulgates, plans, administers, coordinates, and evaluates overall Center scientific, management, and regulatory programs, plans, and policies.

Provides leadership and direction for all Center activities.

Coordinates and directs the Center management, planning, and evaluation systems to assure optimum utilization of Center manpower, financial resources, and facilities.

Directs Center operations for equal employment activities.

2. Insert a new subparagraph *Executive Operations Staff (HFN11)* under the *Office of the Center Director (HFN1)* reading as follows:

Executive Operations Staff (HFN11). Provides executive secretariat support to the Immediate Office of the Center Director, including coordinating executive and legislative correspondence and activities; managing the preparation and coordination of meetings; and preparing background material, graphics, and other information for meetings, speeches, and presentations.

Provides project management support for Centerwide and Agencywide initiatives to improve the quality and timeliness of regulatory reviews and improve team-based management practices.

Provides management support and advice to senior Center management concerning Center programs, including Center extramural contracts and grants activities.

3. Insert a new subparagraph, *Regulatory Affairs Staff (HFN13),* under the *Office of the Center Director (HFN1)* reading as follows:

Regulatory Affairs Staff (HFN13). Initiates, develops, and reviews regulations, policies, procedures, and guidelines that affect the drug approval process.

Serves as the Center's focal point on regulatory issues providing advice and assistance on such matters as scope, applicability, and intents of the Food, Drug, and Cosmetic Act and other laws, regulations, and policies.

4. Delete the subparagraph, *Office of Compliance (HFND),* under the *Center for Drug Evaluation and Research (HFN)* and insert a new subparagraph reading as follows:

Office of Compliance (HFND). Monitors the quality of marketed drugs through product testing, surveillance, and compliance programs.

Advises the Center Director and other Agency officials on FDA's regulatory responsibilities for drugs.

Develops standards for drug industry practices, including Current Good Manufacturing Practice (CGMP) regulations, and ensures their uniform interpretation.

Directs the Center's bioresearch monitoring program for drug products.