

Greetings!

FDA NEWS RELEASE

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FDA Issues Final Rules to Help Patients Gain Access to Investigational Drugs

The U.S. Food and Drug Administration published two rules today that seek to clarify the methods available to seriously ill patients interested in gaining access to investigational drugs and biologics when they are not eligible to participate in a clinical trial and don't have other satisfactory treatment options.

To support the effort to help these patients, the agency also is launching a new Web site where patients and their health care professionals can learn about options for investigational drugs. In general, these options include being treated with a drug that has been approved by FDA, being given an investigational drug as part of a clinical trial, or obtaining access to an investigational drug outside of a clinical trial.

The new rule, "**Expanded Access to Investigational Drugs for Treatment Use**," makes investigational drugs more widely available to patients by clarifying procedures and standards. The other rule, "**Charging for Investigational Drugs Under an Investigational New Drug Application**," clarifies the specific circumstances and the types of costs for which a manufacturer can charge patients for an investigational drug when used as part of a clinical trial or when used outside the scope of a clinical trial.

"With these initiatives, patients will have the information they need to help them decide whether to seek investigational products," said Margaret A. Hamburg, M.D., Commissioner of Food and Drugs. "For patients seeking expanded access to investigational drugs and biologics, the new rules make the process easier to understand."

Clinical trials are studies of drugs and biologics that are still in development and have not yet been approved by the FDA. Many patients enroll in clinical trials to gain access to investigational therapies and contribute to finding out how well an investigational therapy works, and how safe it is for patients. Obtaining a drug or biologic under an expanded access program may be an option for some patients who are not able to enroll in clinical trials.

The FDA has allowed expanded access to experimental drugs and biologics since the 1970s. That access has allowed tens of thousands of patients with HIV/AIDS, cancer, and other conditions to receive promising therapies when no approved alternative is available.

"The final rules balance access to promising new therapies against the need to protect patient safety and seek to ensure that expanded access does not discourage participation in clinical trials or otherwise interfere with the drug development process," said Janet Woodcock, M.D., director of the FDA's Center for Drug Evaluation and Research. "Clinical trials are the most important part of the drug development process in determining whether new drugs are safe and effective, and how to best use them."

Additional Information

[Web site that explains the options for investigational drugs](#)

[Final Rules for Expanded Access to Investigational Drugs for Treatment Use and Charging for Investigational Drugs](#)