

Drug Topics

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FDA issues rules for investigational drugs

By Alaina Scott, Senior Editor

The U.S. Food and Drug Administration (FDA) published two rules recently to help clarify how very ill patients can get access to investigational drugs and biologics when they are not eligible to participate in a clinical trial and do not 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 healthcare professionals can learn about options for investigational drugs. The FDA is giving patients the option of being treated with a drug that has been approved by FDA, receiving an investigational drug as part of a clinical trial, or obtaining access to an investigational drug outside of a clinical trial, it said in a statement.

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 final rule clarifies existing regulations and adds new types of expanded access for treatment use. Under the final rule, expanded access to investigational drugs for treatment use will be available to:

- Individual patients, including in emergencies.
- Patient populations of intermediate size.
- Larger populations under a treatment protocol or treatment-related investigational new drug application (IND).


The other rule, “Charging for Investigational Drugs Under an Investigational New Drug Application,” clarifies the specific circumstances and types of costs for which a manufacturer can charge patients when an investigational drug is used, either as part of a clinical trial or as a therapy outside the scope of a clinical trial. Specifically, this rule amends the IND regulation on charging patients for investigational drugs. The rule revises the charging regulation to:

- Clarify the circumstances under which charging for an investigational drug in a clinical trial is appropriate.
- Set forth criteria for charging for an investigational drug in connection with the different types of expanded access for treatment use described in FDA's final rule on expanded access for treatment use of investigational drugs.
- Clarify what costs can be recovered.

“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, MD, 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.”

The rules go into effect 60 days from date of publication in the *Federal Register*.



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