HINSHAW

FDA Publishes Draft Guidance on Individual Patient Access to Investigational New Drugs

Healthcare Alert | 2 min read
Feb 9, 2015

Last week, the FDA published Draft Guidance for Industry, intended to clarify who may access investigational new drugs ("INDs"). The Final Rule originally published in 2009 on the subject of INDs was intended to increase awareness of expanded access programs concerning patients who lack therapeutic alternatives to serious or life-threatening disease or conditions. This new Draft Guidance clarifies which patients would qualify for access to INDs.

Specifically, the Draft Guidance states that the FDA may permit expanded access to INDs for patients who meet the following criteria, as set forth in 21 CFR 312.305(a) and 312.310(a):

1. The patient to be treated has a serious or immediately life-threatening disease or condition, and there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition.
2. The potential patient benefit justifies the potential risks of the treatment used and those potential risks are not unreasonable in the context of the disease or condition to be treated.
3. Providing the investigational drug for the requested use will not interfere with the initiation, conduct or completion of clinical investigations that could support marketing approval of the expanded access use or otherwise compromise the potential development of the expanded access use.
4. The patient's physician must determine that the probable risk to the person from the IND is not greater than the probable risk from the disease or condition.
5. FDA must determine the patient cannot obtain the investigational drug another IND or protocol.

In order to assist physicians in requesting expanded access for individual patients, the FDA has also developed a new Individual Patient Expanded Access IND form ("Form 3926"). Because prior forms allowed requests for expanded access to not only individuals, but to intermediate-sized patient populations and to large patient populations, the FDA created the new Form 3926 to eliminate the difficulty some physicians have had in requesting expanded access for individual patients.

Under the Draft Guidance, when an emergency situation arises to the extent a physician does not have time to complete and submit Form 3926, a physician may request, from the appropriate FDA review division, the use of an IND by telephone or any other rapid means of communication. However, the physician would also be required to complete the Form 3926 within 15 working days of the FDA's authorization for such expanded excess use.

Prior to submitting Form 3629, a physician would be required to obtain a letter of authorization from the drug manufacturer stating that it will supply the IND to the physician for the patient needing expanded access. It is important that physicians understand that when requesting expanded access for an individual patient, the physician is considered a sponsor-investigator and is responsible for complying with the responsibilities for sponsors and investigators, including submitting IND safety reports and all other required records and reports. Further, the physician is required to obtain the informed consent from the patient pursuant to 21 CFR §50.25, which is an expansion of the basic elements of informed consent geared toward clinical trials for new drugs.

The Draft Guidance is not yet final and will be open for comments for 60 days.

If you have any questions concerning this Alert, contact your regular Hinshaw attorney.

This alert has been prepared by Hinshaw & Culbertson LLP to provide information on recent legal developments of interest to our readers. It is not intended to provide legal advice for a specific situation or to create an attorney-client relationship.