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Drug Safety and Availability > FDA working with manufacturers to withdraw Zinbryta from the market in the United States

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On March 2, Biogen and Abbvie announced a voluntary withdrawal of Zinbryta (daclizumab), a multiple sclerosis (MS) drug, from the global market, noting concern about the drug's evolving benefit/risk profile. As a result, FDA is working closely with the manufacturers to help ensure a well-organized withdrawal from the market in the United States, and to ensure that health care professionals have the information they need to carefully transition their patients using Zinbryta to another treatment. No new patients will start taking Zinbryta or participate in clinical studies. The company has begun notifying health care professionals and patients, and the drug will be available for patients as needed until April 30, 2018.

Patients using Zinbryta should not stop their medication without talking with their doctor and should contact their doctor immediately if they have any new and unexplained symptoms. Any questions or concerns about the withdrawal can be directed to the manufacturers' service center at **1-800-456-2255** or the manufacturer's website at www.zinbryta.com. We understand that this may be a difficult situation for some patients and will continue

to work closely with the manufacturers throughout the withdrawal process.

The complex safety profile of Zinbryta has been recognized since the time of FDA approval. The drug's safety profile led to an indication of use generally limited to patients who have had an inadequate response to two or more multiple sclerosis drugs, to a boxed warning about the risk of liver injury and of other immune-mediated disorders, and to a Risk Evaluation and Mitigation Strategy making the drug only available through a restricted distribution program. FDA has continuously monitored adverse events associated with use of Zinbryta and has updated product labeling as new information became available.

Recently, the European Medicines Agency announced a recall of Zinbryta following 12 reports of serious inflammatory brain disorders worldwide. FDA is aware of these reports and is conducting a review of similar events. As the manufacturers move forward the withdrawal plan, any additional important information will be made available to the public.

FDA asks health care professionals and consumers to report any adverse reactions or quality problems to the FDA's MedWatch program:

- Complete and submit the report online at www.fda.gov/medwatch/report.htm.
- Download and complete the form, then submit it via fax at 1-800-FDA-0178.