HEW NEWS

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

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(Food and Drug Administration)
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In response to a court directive, the Food and Drug Administration today invited public testimony on the legal and scientific status of Laetrile, a substance widely promoted as a cancer "cure."

Also known as amygdalin and vitamin B-17, Laetrile occurs naturally in the pits of apricots, peaches and bitter almonds. The substance has been promoted as a cancer "cure" for about 25 years. Recent promoters claim it also prevents cancer.

Written testimony and oral argument will be received on two specific questions: 1) Is Laetrile generally recognized by experts as a safe and effective anti-cancer drug?; and 2) Is Laetrile, by virtue of its marketing before the 1962 Food, Drug and Cosmetic Act, exempt from that law's requirement that a drug be shown by scientific evidence to be safe and effective before it can be marketed?

FDA will accept written testimony on these issues until March 25. Written replies to that testimony will be accepted until April 22.

Oral argument on the issues raised by the written testimony will be held before a representative of the Commissioner of FDA in Kansas City, Missouri, on May 2. Anyone who wants to make a presentation at that time must file a written notice by April 22.

FDA's Bureau of Drugs will participate in the proceedings as a proponent of the position that Laetrile has not been proved safe and effective as an anti-cancer drug and that it is not exempt from FDA regulation.

In announcing the invitation for public testimony, FDA emphasized that "this proceeding...is being undertaken by FDA solely because the Agency was directed to do so by the Court of Appeals."

FDA made clear that the proceedings will not deter the Agency from continuing to take regulatory action against commercial distribution of Laetrile.

The Court of Appeals for the Tenth Circuit in October, 1976, ordered FDA to compile an administrative rulemaking record concerning Laetrile. The written testimony and oral arguments are to be a part of this record. When complete, the record will be submitted to the U. S. District Court in Oklahoma City. The case before the district and appeals courts involves a cancer patient seeking to obtain Laetrile.

Several cases similar to this one have been instituted in other Federal courts. In the majority of these cases, the Court has ruled in FDA's favor. No court has authorized the sale of Laetrile in the United States or its importation for commercial distribution.

Early promoters of Laetrile claimed that it worked by seeking out cancerous cells and destroying them with cyanide, a deadly chemical contained in Laetrile. The promoters claimed that healthy cells were safe from Laetrile because the cyanide release could only be triggered by a substance found in cancerous cells but not present in healthy cells.

Later the promoters changed their approach to claim that cancer is caused entirely by a deficiency of "vitamin B-17" and that Laetrile is this "vitamin."

Scientists have never found any evidence to support either of these theories.

No professional dietetic or nutrition group has ever recognized Laetrile as a vitamin.

And, despite intensive effort over many years, the FDA, the American Medical Association, the American Cancer Society, the National Cancer Institute and independent researchers have been unable to find any scientific evidence that Laetrile has any effect on cancer.

Laetrile is the most tested of all cancer "cures." The National Cancer Institute alone has tested Laetrile in animals on five separate occasions between 1957 and 1975. Four independent cancer research centers which undertook additional studies in 1975 have found no evidence that Laetrile is effective in treating cancer.

Under U.S. law, no drug intended for use against cancer or any other disease can be regarded as safe for testing in humans until it first shows some indication of effectiveness in test animals.

All 26 anti-cancer drugs approved by FDA since 1962 were first shown to be effective in animals before being tested for safety and effectiveness in humans.

Notice of the Laetrile proceedings will be published in the FEDERAL REGISTER February 18, 1977.

Written testimony can be submitted to the office of the FDA Hearing Clerk, Room 4-65, 5600 Fishers Lane, Rockville, Maryland 20857. Copies of all testimony will be maintained there and at FDA offices in Brooklyn, New York; Atlanta, Georgia; Chicago, Illinois; Kansas City, Missouri; Los Angeles, California; and Seattle, Washington.

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