

March 14, 2010

SIR FACT SHEET

Message From SIR President: Report on Ethiodol Shortage

Savage Laboratories®, a division of Nycomed and the sole U.S. supplier of Ethiodol (Lipiodol), stopped production in February 2010. We do not know why. Ethiodol (Lipiodol) is a product of Guerbet, whose headquarters is located in Villepinte, France. In the remainder of the world Ethiodol continues to be widely available.

Multiple SIR members alerted the Society of this critical shortage early this month. Members are strongly encouraged to register their shortage with the U.S. Food and Drug Administration (FDA) at www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm142398.htm.

Personal importation for individual use is legal if the proper protocol is followed. Please see this Web link for more information:

www.fda.gov/ForIndustry/ImportProgram/ImportPolicyandInformationbyProduct/default.htm

SIR and/or its members are in active discussion with Guerbet USA, FDA and Congress to find a reliable permanent new source of Ethiodol. The SIR effort is being coordinated by SIR member David Eschelmann, M.D., FSIR, at Thomas Jefferson University, Philadelphia, Pa. We will provide members with more information as we have it.

If you have questions or comments, please contact Tricia McClenny, SIR interim executive director, via e-mail at comm@SIRweb.org.

INFO FOUND AT LINK

Import Policy and Information by Product

Policy on Importation of Drugs (1998)

Information on Importation of Drugs

Prepared by the Division of Import Operations and Policy, FDA

The United States Federal Food, Drug and Cosmetic Act (Act) (21 U.S.C. section 331) prohibits the interstate shipment (which includes importation) of unapproved new drugs. Thus, the importation of drugs that lack FDA approval, whether for personal use or otherwise, violates the Act. Unapproved new drugs are any drugs, including foreign-made versions of U.S.-approved drugs, which have not been manufactured in accordance with and pursuant to an FDA approval. Under the Act, FDA may refuse admission to any drug that “appears” to be unapproved, placing the burden on the importer to prove that the drug sought to be imported is in fact approved by FDA. Absent evidence that the specific drugs sought to be imported from a foreign country have been manufactured pursuant to an approved new drug application, in the manufacturing facility permitted under the application, such drugs would appear to be unapproved new drugs subject to FDA enforcement action.

The use of FDA resources to provide comprehensive coverage of unapproved new drugs imported for personal use is generally not justified; however, the agency developed guidance in its Regulation Procedures Manual (RPM)

(1)

www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProceduresManual/UCM074300.pdf

(2)

http://www.fda.gov/ForIndustry/ImportProgram/compliance_ref/rpm_new2/ch9pers.html

titled, “Coverage of Personal Importations” (copy enclosed). This guidance sets forth the agency’s enforcement priorities related to the personal importation of unapproved new drugs, with enforcement being focused on products apparently intended for the commercial market and on fraudulent products and those that pose an unreasonable health risk. The guidance recognizes that circumstances may exist where, for example, a person has begun treatment with an unapproved drug in a foreign country

or suffers from a condition for which there exists no FDA-approved treatment. If such circumstances can be substantiated, as the text of the guidance quoted below notes, the guidance suggests that refraining from taking action against the illegal importation, in the exercise of enforcement discretion, may be appropriate. The guidance document is not, however, a license for individuals to import unapproved (and therefore illegal) drugs for personal use into the United States and, even if all the factors noted in the guidance are present, the drugs remain illegal and FDA may decide that such drugs should be refused entry or seized. Similarly, the factors noted in the guidance, and documentation that should be obtained from individuals importing the drugs, are not mandatory requirements. They are intended to guide FDA enforcement discretion and should not be represented as binding requirements. The statements in the RPM are intended only to provide operating guidance for FDA personnel and are not intended to create or confer any rights, privileges, or benefits on or for any private person.

That said, FDA's guidance for coverage of personal importations of unapproved drugs identifies several factors that should be considered by FDA personnel when determining whether to exercise enforcement discretion and refrain from taking action against the importation of unapproved drugs. The General Guidance Section states that FDA should consider not taking enforcement actions against such importation:

“when 1) the intended use [of the drug] is unapproved and for a serious condition for which effective treatment may not be available domestically either through commercial or clinical means; 2) there is no known commercialization or promotion to persons residing in the U.S. by those involved in the distribution of the product at issue; 3) the product is considered not to represent an unreasonable risk; and 4) the individual seeking to import the product affirms in writing that it is for the patient's own use (generally not more than 3 month supply) and provides the name and address of the doctor licensed in the U.S. responsible for his or her treatment with the product or provides evidence that the product is for the continuation of a treatment begun in a foreign country.” (Emphasis added.)

The above guidance does not specify that a U.S. citizen may import an unapproved drug only with a prescription from a U.S.-licensed physician, or that a foreign citizen may import an unapproved new drug only with a foreign prescription. Rather, to ensure that the importation is for personal use only (and not for resale), and to ensure that the use of the unapproved new drug sought to be imported into the United States is supervised and does not represent an unreasonable risk, the guidance provides that the individual affirm in writing that the drug is for his or her personal use and provide either the name and address of the U.S.-licensed physician who will supervise its use or some evidence that the treatment was begun in a foreign country and that the drugs are being imported to continue/conclude the already begun treatment. Thus, while not the only documentation, either a U.S. or foreign prescription, along with an affirmation of personal use, could be supplied as evidence that this factor exists.

The guidance also provides that the importation should generally not represent more than a three-month supply of the unapproved products. The purpose for this provision is in keeping with the intent that the guidance relate to only drugs for personal use, not commercial distribution. As the document sets forth only guidance, the three-month limitation is not a “requirement” or a “restriction.” If an individual presents evidence that he or she requires more than a three-month supply for the full treatment of his or her illness, and it appears that the reordering of a one- or two-month additional amount may be inappropriate, FDA may consider the release of the full amount. Similarly, if a foreign traveler to the United States seeks to import unapproved drugs during his or her stay in the United States, the amount sought to be imported should represent the amount needed for personal use during the U.S. visit. Where the evidence appears to indicate that the drugs may be imported for commercial distribution, the guidance provides that FDA should refuse admission of such drugs.

It must be emphasized that the intent of the personal use importation guidance is to save FDA resources and to generally permit, through the exercise of enforcement discretion, medical treatments sought by individuals that are not otherwise available in the United States (where such treatments are not promoted/commercialized in the United States). Thus, foreign-made chemical versions of drugs available in the United States are not intended to be covered by the policy. For example, a person may decide that his or her FDA-approved heart medication is cheaper in Mexico and attempt to import the

unapproved version of the drug from Mexico. FDA cannot ensure that such products have been properly manufactured and are effective; therefore, given that such products are available in the United States, their use would present an unreasonable risk and the guidance would not apply (unless the person seeking their importation could establish that the drugs were needed to refill a prescription while traveling or were otherwise needed while traveling).

Likewise, a drug such as Valium is available in the United States and, as such, a foreign-made version of the U.S.-approved drug would not generally be considered a candidate to be permitted entry under the guidance. However, because the U.S. Drug Enforcement Administration (DEA) may have specific requirements that apply to the importation of controlled substances such as Valium, FDA's guidance on personal importations specifically provides that controlled substances should be returned to Customs for handling.

FDA will not approve a particular form or format for information to accompany personal use shipments or approve any scheme proposed to facilitate the importation of an unapproved new drug, because to do so would be to imply that such importation meets FDA's personal importation guidance and is legally permitted.

Congress has the power to determine which articles may be permitted importation into the United States from a foreign source and the terms on which the importation will occur. An article subject to the Federal Food, Drug and Cosmetic Act is still in "interstate commerce" even if it is purchased before being shipped across state lines. This is true even if the article is intended solely for personal consumption. Therefore, the Act properly regulates personal articles imported into the United States for personal consumption. The Act also prohibits the importation into the United States of any unapproved new drug.

We appreciate that there is a significant cost differential between drugs available here and those in other countries. However, many drugs sold in foreign countries as "foreign versions" of approved prescription drugs sold in the United States are often of unknown quality with inadequate directions for use and may pose a risk to the patient's health. FDA approves a drug on the basis of scientific data proving it to be safe and effective. FDA-approved labeling provides information on how and when the drug can be used to maximize effectiveness and minimize any harmful side effects. The manufacturing facilities and procedures for approved products are also carefully regulated by FDA to ensure product integrity. Since FDA cannot assure the consumer that the drug purchased in the foreign country would be the same product his or her physician's prescription is written for, we recommend the product covered by the prescription be acquired in the United States.

Drafted: Marvin A. Blumberg, HFC-170, 4/3/98