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M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: JAN 22 1997

TO: Robert J. Wolters, Ph.D.
Chemist
Division of Cardio-Renal Drug Products (HFD-110)

FROM: Director
Division of OTC Drug Products (HFD-560)
Office of Drug Evaluation V

SUBJECT: Levmetamfetamine (L-desoxyephedrine)

We have learned that the USAN Council proposed that the name for the over-the-counter (OTC) nasal decongestant ingredient, L-desoxyephedrine, should be changed to Levmetamfetamine. My staff and I are very concerned that the new name, Levmetamfetamine, will draw the attention of potential drug abusers to these OTC nasal decongestant drug products if they contain "metamfetamine" in their name.

During a telephone conversation with Mr. Cazemiro Martin of my staff on December 13, 1996, you indicated that the USAN Council voted unanimously to adopt the International Nomenclature Name (INN), Levmetamfetamine, in place of L-desoxyephedrine. You indicated that the Council's decision for the name change was based on the following: (1) The ingredient is nonaddictive, (2) the new name is consistent with INN policy, and (3) any other name for desoxyephedrine may be confusing.

Although L-desoxyephedrine is a nonnarcotic substance (21 CFR 1308.22), we are concerned that an OTC drug product label containing the name "Levmetamfetamine" may encourage intentional misuse of the nasal decongestant drug product by individuals who may not understand the differences in the activity of the optical isomers of methamphetamine. We believe that OTC drug product labeling bearing the name Levmetamfetamine may also encourage the attempt by a discreet user population to extract methamphetamine from such drug products. Further, DEA is aware of published literature describing how to synthesize methamphetamine from the OTC nasal decongestant drug product (Vick's Inhaler) which contains L-desoxyephedrine.

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In addition, we believe that designation of the term "Levemetamfetamine" may actually cause more confusion for consumers than the current name, L-desoxyephedrine. Besides encouraging misuse in a discreet population, the proposed new name may cause consumers to mistakenly associate the product with illegal street drugs, and therefore choose not to use this product for relief from nasal congestion.

We do not believe that the new proposed name, Levmetamfetamine, is a suitable name for a drug product available OTC or that any name other than Levmetamfetamine for desoxyephedrine would be confusing. The name L-desoxyephedrine has been used for many years. There would be no confusion if the name remained the same. Other less confusing, acceptable names would be lesoxyephedrine or levodesoxyephedrine.

Both FDA and DEA are very concerned with the increased use of methamphetamine in the United States and with the large-scale diversion of some OTC drug products for illicit use in the manufacture of the controlled substances methamphetamine and methcathinone. For example, in the Federal Register of July 27, 1995 (60 FR 38643) (see attachment), the agency discussed several reports from the U.S. Department of Justice, Drug Enforcement Administration (DEA) that indicated large-scale diversion of OTC ephedrine-containing drug products as the primary precursor utilized in the synthesis of the controlled substances methamphetamine and methcathinone. The agency also discussed numerous reports involving young people who have overdosed by using OTC ephedrine products promoted as a stimulant or for weight control, or by using such products for recreational purposes in high doses and on a regular basis. We are concerned about similar potential "promotion" and the intentional misuse of OTC inhaler drug products that contain "Levmetamfetamine" in their label.

During a recent telephone conversation with Mr. Martin, a representative of DEA's Office of Diversion Control indicated that DEA strongly agrees with our concern that the proposed new name, Levmetamfetamine, may lead additional individuals to attempt to extract methamphetamine from an OTC nasal decongestant drug product containing this ingredient. The DEA representative pointed out that although one such product, Procter & Gamble's Vick's Inhaler, does not contain sufficient amount of L-desoxyephedrine to extract a significant amount of methamphetamine, an OTC nasal decongestant drug product bearing

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the active ingredient name "Levmetamphetamine" poses a potential abuse problem. According to the DEA representative, DEA is prepared (upon request of the USAN Council) to provide additional information to support the recommendation that Levmetamphetamine not be selected as the new name for L-desoxyephedrine.

Based on both FDA's and DEA's concerns about the illicit use of ephedrine products in the manufacture of methamphetamine; the extensive abuse of methamphetamine as reported in several DEA publications in 1995 and 1996 (see attachments); and the possible negative connotation by some consumers that a product labeled with an active ingredient designated as "levmetamphetamine" is associated with illegal street drugs, we strongly object to the USAN Council's recommendation to adopt "Levmetamphetamine" as the nonproprietary name for L-desoxyephedrine.

If we can be of further assistance concerning this matter, please contact Mr. Cazemiro Martin of my staff at 301-827-2274.

Please keep us informed of the USAN Council's position on this name.


Debra Bowen, M.D.

Attachments