



ABBOTT

Abbott Laboratories
100 Abbott Park Road
Abbott Park, Illinois 60064-3500

6036 98 APR 27 A9:38

FAX (301) 594-3215

Certified Mail Z146 318 981

April 17, 1998

Food and Drug Administration
Dockets Management Branch (HFA-305)
12420 Parklawn Dr., Room 1-23
Rockville, MD 20857

Dear Sirs:

RE: Docket No. 98N-0148, International Drug Scheduling

This is submitted in response to the Food and Drug Administration's request for comments concerning the international scheduling of several drug substances including ephedrine.

Abbott Laboratories manufactures Ephedrine Sulfate Injection, USP, 50 mg/mL, 1 mL single dose ampuls. The ampuls are sold either in cases of 100 or 400 or packaged in anesthesia trays. Ephedrine and ephedrine products are regulated in the US as a prescription drug. They are also regulated by US and International law as a precursor chemical subject to record keeping, reporting, security, and importing/exporting requirements. Ephedrine is not, nor do we believe it should be, scheduled and subject to the same requirements as a controlled substance.

Ephedrine is a sympathomimetic drug that stimulates both alpha and beta receptors. Pharmacologic effects include bronchodilation, increased blood pressure, and relaxation of GI smooth muscle. It is most commonly used in the treatment of mild asthma and hypotension due to anesthesia, sympathomimectomy or following over-dosage of certain hypotensive agents.

98N-0148

C15

a

Food And Drug Administration
April 17, 1998
Page 2

Central nervous system (CNS) adverse effects in normal doses include nervousness, apprehension, fear, tension, excitation, restlessness, weakness, irritability, talkativeness, or insomnia. Large parenteral doses may cause confusion, delirium, hallucinations, or euphoria. Other adverse effects include headache, respiratory difficulty, feeling of warmth, dry mouth, anorexia, nausea, or vomiting. Abuse of ephedrine has produced psychic dependence.

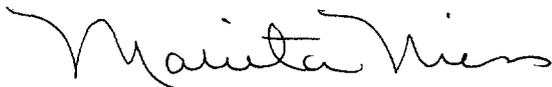
Over-the-counter ephedrine preparations have a history of use for the illicit manufacture of methamphetamine due, in part, to their accessibility to the general public. The Drug Enforcement Administration listed chemical requirements address these concerns in the US.

The injectable form of ephedrine has no known history of abuse in the US. Injectable ephedrine products are used primarily by hospitals and surgery centers who receive them from manufacturers and wholesalers. All of these entities must comply with prescription drug requirements. Hospitals and surgery centers must document drug administration via prescriptions and medical records. Excessive consumption of injectable ephedrine without corresponding medical records should be noted. Also, there is limited access to the product in the hospital pharmacy and anesthesia/surgery area.

If ephedrine injection becomes a controlled substance, there is the potential that ephedrine ampules will be removed from anesthesia trays because of limited space in controlled substance storage areas. This would require an additional step to procure the drug for use in surgery. Because most institutions restrict procurement of controlled substances to certain personnel, this could cause a delay in providing the drug to the surgical area, which would affect efficient and effective patient care.

In summary, Abbott Laboratories does not agree with the proposal to schedule ephedrine. There are already controls in place to address the abuse of ephedrine as a precursor to controlled substances such as methamphetamine. We believe the potential for abuse of ephedrine injection is extremely low, as the product has limited distribution, and use of the drug can be traced through required records.

Sincerely,



Marieta Niess, Director
Controlled Drugs, D-387
Corporate Regulatory Affairs

ABBOTT

Abbott Laboratories
Dept. 387 Bldg. AP6C-1
100 Abbott Park Road
Abbott Park, IL 60064-3500

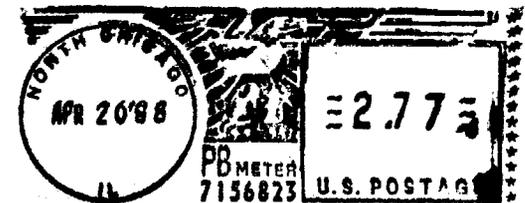
CERTIFIED

Z 146 318 981

MAIL

RETURN RECEIPT REQUESTED

**FIRST
CLASS**



FOOD AND DRUG ADMINISTRATION
DOCKETS MANAGEMENT BRANCH (HFA-305)
12420 PARKLAWN DR ROOM 1-23
ROCKVILLE MD 20857

