Summary

It is recommended that:

1. The drug be discontinued for children under 12 years of age. No valid, well controlled and double blind, studies were performed delineating the safety and efficacy of diphenoxylate hydrochloride with atropine sulfate (0.025 mg.) for children.

2. A warning label to indicate the dangerous nature of the drug on children e.g. "Warning: Keep Out of Reach of Children, Dangerous Drug."

3. Use in pregnancy and lactation is contraindicated unless studies are available to indicate safety.

4. Diphenoxylate hydrochloride with atropine sulfate is a safe and effective drug for diarrhea when used as an adjuvant to specific therapy for the underlying disorder causing diarrhea in adults.

5. Labeling changes are necessary as enumerated in labeling section. The labeling is in dire need of updating, correction, amendment, additions and deletion of dosage for children.

6. Lomotil is no more effective than other narcotics. The only advantage it enjoys is that of markedly decreased addiction potential over other narcotic drugs used in diarrheal disease.

7. Atropine, even in subtherapeutic doses, should be removed from the mixture especially to obviate mortality in children.

A. L. KAMINSKY, M.D.,
Drug Surveillance Branch/DMR.

SUMMARY OF REPORTS

Date Summary Completed: 10/24/67.
NDA 12-462 (tablets), 12-699 (liquid).
G. D. Searle & Co., Chicago, Ill., AF 13-505.
Original approval date: 9/15/60 (12-462); 1/17/61 (12-699).

Name of Drug.—Trade: Lomotil.

Generic: diphenoxylate hydrochloride and atropine sulfate.

Dosage forms and route of administration.—

1. Tablets, oral; diphenoxylate HCl 2.5 mg., atropine SO_4 0.025 mg.
2. Liquid, oral; diphenoxylate HCl 2.5 mg., atropine SO_4 0.025 mg. per 5 cc.

Category or Use of Drug.—Antidiarrheal (exempt narcotic)

Date of Reports.—

1. April 18, 1966
2. May 17, 1966
3. May 24, 1966
4. June 6, 1966
5. June 14, 1966
6. June 15, 1966
7. June 20, 1966
8. July 14, 1966
9. March 2, 1967
10. April 19, 1967
11. April 27, 1967

Reason for Reports.—Adverse reaction reports

Material Reviewed.—Report as follows:

Searle Case No.	*Dates of Reports*	*Searle Case No.*	*Dates of Reports*
A. LO 2-66	1. 4/18/66	G. LO 8-66	1. 6/20/66
	2. 6/15/66		2. 7/14/66
B. LO 3-66	1. 6/6/66	H. LO 2-67	1. 3/2/67
C. LO 4-66	1. 5/17/66		2. 4/19/67
D. LO 5-66	1. 5/24/66	I. LO 4-67	1. 4/19/67
	2. 6/15/66		2. 4/27/67
E. LO 6-66	1. 6/14/66		
F. LO 7-66	1. 6/20/66		
	2. 7/14/66		

Clinical Evaluation.

A. Searle Case #LO 2-66 dated 4/18/66 and 6/15/66.

Adverse reaction report follow-up (of 3/18/66 report) of fatality in a 3 year old child who had received Lomotil tablets under the supervision of C. W. Jarvis,