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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

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Certifier J. Corde

[Docket No. 2005N-0331]

Able Laboratories, Inc.; Withdrawal of Approval of Ten
Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of ten abbreviated new drug applications (ANDAs) held by Able Laboratories, Inc. (Able Labs), One Able Dr., Cranbury, NJ 08512. Able Labs has initiated a class II recall of the products covered by these ANDAs. The company has requested that the applications be withdrawn and has waived its opportunity for a hearing.

DATES: Effective [insert date of publication in the FEDERAL REGISTER].

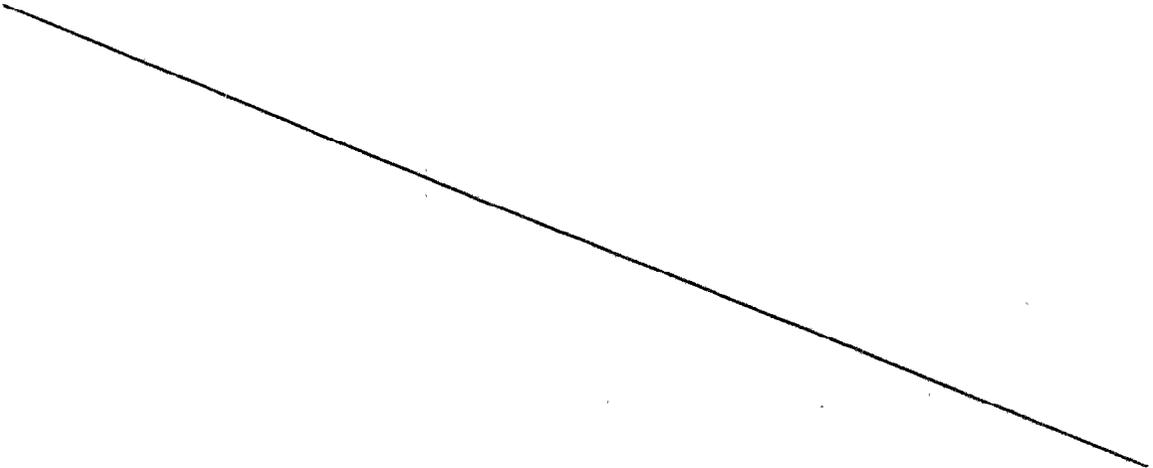
FOR FURTHER INFORMATION CONTACT:

Florine P. Purdie,
Center for Drug Evaluation and Research (HFD-7),
Food and Drug Administration,
5600 Fishers Lane,
Rockville, MD 20857,
301-594-2041.

SUPPLEMENTARY INFORMATION: On May 25, 2005, Able Labs notified the agency that, because of improper laboratory practices and noncompliance with standard operating procedures, Able Labs was initiating a voluntary, class II recall of the products covered by the ANDAs listed in the table of this document. The company voluntarily requested withdrawal of approval of the ANDAs under § 314.150(d) (21 CFR 314.150(d)), and waived its opportunity for a hearing, provided under § 314.150(a) and (b). The following ANDAs are affected by this action:

ANDA No.	Drug
40-395	Diphenoxylate Hydrochloride (HCl) and Atropine Sulfate Tablets USP, 2.5 milligrams (mg)/0.025 mg
40-404	Methylphenidate HCl Tablets USP, 5 mg, 10 mg, and 20 mg
40-407	Prochlorperazine Suppositories USP, 2.5 mg, 5 mg, and 25 mg
40-452	Acetaminophen and Codeine Phosphate Tablets USP, 300 mg/30 mg
40-459	Acetaminophen and Codeine Phosphate Tablets USP, 300 mg/60 mg
71-780	Clorazepate Dipotassium Tablets USP, 3.75 mg
71-781	Clorazepate Dipotassium Tablets USP, 7.5 mg
71-782	Clorazepate Dipotassium Tablets USP, 15 mg
75-838	Propoxyphene Napsylate and Acetaminophen Tablets USP, 100 mg/650 mg
76-032	Methylphenidate HCl Extended-Release Tablets USP, 20 mg

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) and under authority delegated to the Director, Center for Drug Evaluation and Research (21 CFR 5.105(a)), approval of the ANDAs listed in the table of this document, and all amendments and supplements thereto, is withdrawn, effective [insert date of publication in the FEDERAL REGISTER]. Thereafter, distribution of the products in interstate commerce without approved applications is illegal and subject to regulatory action. Also, on the basis of the circumstances described in this document that led to the recall of the products and their subsequent removal from the market, the agency will remove the products from the agency's list of drug products with effective approvals, published under the title "Approved Drug Products With Therapeutic Equivalence Evaluations." This document serves as notice of the removal of the products covered by the ANDAs listed in this document from the list of approved drug products. Distribution of these products



in interstate commerce without approved applications is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the act (21 U.S.C. 355(a) and 331(d))).

Dated: 8.15.05

August 15, 2005.

Steven Galson

Steven Galson,
Director,
Center for Drug Evaluation and Research.

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL

[Signature]