

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
[Docket No. 2006N-0010]

Display Date	1-18-06
Publication Date	1-19-06
Case No.	R. LINDSAY
	VDM

Able Laboratories, Inc.; Withdrawal of Approval of 43 Abbreviated
New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 43 abbreviated new drug applications (ANDAs) held by Able Laboratories, Inc. (Able Labs), One Able Dr., Cranbury, NJ 08512. The drug products are no longer marketed, and Able Labs has requested that the approval of the applications be withdrawn.

DATE: Effective [~~insert date 30 days after~~ date of publication in the FEDERAL REGISTER.]

1-18-06
1-19-06
1-18-06

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: The applications listed in the table in this document are no longer marketed, and Able Labs has requested that FDA withdraw approval of the applications. The

company has also, by its request, waived its opportunity for a hearing.

Application No.	Drug
40-390	Butalbital, Acetaminophen, and Caffeine Tablets USP, 50 milligrams (mg)/325 mg/40 mg
40-394	Butalbital, Acetaminophen, and Caffeine Tablets USP, 50 mg/500 mg/40 mg
40-402	Phentermine Hydrochloride (HCl) Tablets USP, 37.5 mg
40-403	Phentermine HCL Capsules USP, 30 mg (powder)
40-413	Methocarbamol Tablets USP, 500 mg and 750 mg
40-421	Carisoprodol Tablets USP, 350 mg
40-427	Phentermine HCl Capsules USP, 30 mg (beads)
40-449	Promethazine HCl Suppositories USP, 50 mg
40-464	Hydrocodone Bitartrate and Acetaminophen Tablets USP, 7.5 mg/325 mg and 10 mg/325 mg
40-469	Hydrocodone Bitartrate and Acetaminophen Tablets USP, 7.5 mg/750 mg
40-473	Hydrocodone Bitartrate and Acetaminophen Tablets USP, 10 mg/500 mg
40-474	Hydrocodone Bitartrate and Acetaminophen Tablets USP, 7.5 mg/650 mg

Application No.	Drug
40-476	Hydrocodone Bitartrate and Acetaminophen Tablets USP, 10 mg/650 mg
40-477	Hydrocodone Bitartrate and Acetaminophen Tablets USP, 5 mg/500 mg
40-478	Hydrocodone Bitartrate and Acetaminophen Tablets USP, 5 mg/325 mg
40-483	Bethanechol Chloride Tablets USP, 10 mg
40-485	Bethanechol Chloride Tablets USP, 25 mg
40-490	Hydrocodone Bitartrate and Acetaminophen Tablets USP, 7.5 mg/500 mg
40-492	Bethanechol Chloride Tablets USP, 5 mg
40-497	Phentermine HCl Capsules USP, 15 mg
40-504	Promethazine HCl Suppositories USP, 12.5 mg and 25 mg
40-509	Bethanechol Chloride Tablets USP, 50 mg
40-529	Methamphetamine HCl Tablets USP, 5 mg
40-539	Theophylline Extended-Release Tablets, 600 mg
40-543	Theophylline Extended-Release Tablets, 400 mg
40-546	Theophylline Extended-Release Tablets, 450 mg
40-548	Theophylline Extended-Release Tablets, 300 mg

Application No.	Drug
40-558	Promethazine HCl Tablets USP, 12.5 mg, 25 mg, and 50 mg
40-559	Hydroxyzine HCl Tablets USP, 10 mg
40-562	Hydroxyzine HCl Tablets USP, 25 mg
40-563	Hydroxyzine HCl Tablets USP, 50 mg
76-114	Indomethacin Extended-Release Capsules USP, 75 mg
76-121	Lithium Carbonate Capsules USP, 300 mg
76-382	Lithium Carabonate Extended-Release Tablets USP, 300 mg
76-462	Metronidazole Extended-Release Tablets, 750 mg
76-505	Metronidazole Capsules, 375 mg
76-519	Metronidazole Tablets USP, 250 mg and 500 mg
76-528	Butalbital, Acetaminophen, Caffeine, and Codeine Phosphate Capsules, 50 mg/325 mg/40 mg/30 mg
76-544	Naproxen Sodium Tablets USP, 275 mg and 550 mg
76-666	Indomethacin Capsules USP, 25 mg and 50 mg
76-814	Dextroamphetamine Sulfate Extended-Release Capsules, 5 mg, 10 mg, and 15 mg
76-823	Lithium Carbonate Capsules USP, 150 mg, 300 mg, and 600 mg

Application No.	Drug
76-907	Atenolol Tablets USP, 25 mg, 50 mg, and 100 mg

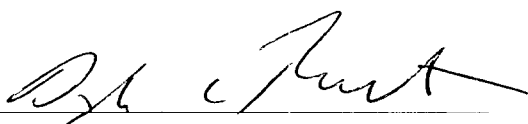
Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) and under authority delegated to the Director, Center for Drug Evaluation and Research, by the Commissioner of Food and Drugs, approval of the applications listed in the table in

this document, and all amendments and supplements thereto, is hereby withdrawn, effective [~~insert date 30 days after~~ date of publication in the FEDERAL REGISTER].

*per
T Friths
1-13-06*

Dated: 1/04/06

January 4, 2006.



Douglas C. Throckmorton,
Deputy Director,
Center for Drug Evaluation and Research.

[FR Doc. 06-????? Filed ??-??-06; 8:45 am]
BILLING CODE 4160-01-S

