



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0021]

Actavis Totowa LLC, et al.; Withdrawal of Approval of Abbreviated New Drug Applications for Prescription Pain Medications Containing More than 325 Milligrams of Acetaminophen

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 108 abbreviated new drug applications (ANDAs) for prescription pain medications containing more than 325 milligrams (mg) of acetaminophen. The holders of these ANDAs have voluntarily requested that approval of these applications be withdrawn and have waived their opportunity for a hearing.

DATES: Effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Rachel Turow, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6236, Silver Spring, MD 20993-0002, 301-796-5094.

SUPPLEMENTARY INFORMATION: In the Federal Register of January 14, 2011 (76 FR 2691), FDA announced its plans to reduce the maximum dosage unit strength of acetaminophen in prescription drug products. The notice announced FDA's conclusion that, based on a reevaluation of the relative risks and benefits of prescription acetaminophen products, fixed-combination prescription drugs containing more than 325 mg of acetaminophen per dosage unit (tablet or capsule) do not provide a sufficient margin of safety to protect the public against the

serious risk of acetaminophen-induced liver injury. Accordingly, we asked product sponsors to limit the maximum amount of acetaminophen per dosage unit to 325 mg and, for those products containing more than 325 mg of acetaminophen per dosage unit, to submit requests that FDA withdraw approval of their applications under § 314.150(d) (21 CFR 314.150(d)). FDA asked that all such requests be made before January 14, 2014. Table 1 lists the applications for which FDA has received such requests. The sponsors of the applications listed in table 1 have also waived their opportunity for a hearing.

Table 1.--Applications for Which Withdrawal of Approval Has Been Requested

Application No.	Drug Product(s)	Applicant or Holder
ANDA 040199	Acetaminophen and Oxycodone Hydrochloride Capsules, 500 mg/5 mg	Actavis Totowa LLC 200 Elmora Ave. Elizabeth, NJ 07207
ANDA 040748	Acetaminophen and Hydrocodone Bitartrate Tablets, 500 mg/7.5 mg	Amneal Pharmaceuticals 85 Adams Ave. Hauppauge, NY 11788
ANDA 040754	Acetaminophen and Hydrocodone Bitartrate Tablets, 650 mg/7.5 mg	Do.
ANDA 040757	Acetaminophen and Hydrocodone Bitartrate Tablets, 650 mg/10 mg	Do.
ANDA 040769	Acetaminophen and Hydrocodone Bitartrate Tablets, 750 mg/7.5 mg	Do.
ANDA 040789	Acetaminophen and Oxycodone Hydrochloride Tablets, 500 mg/7.5 mg Acetaminophen and Oxycodone Hydrochloride Tablets, 650 mg/10 mg	Do.
ANDA 040813	Acetaminophen and Hydrocodone Bitartrate Tablets, 500 mg/10 mg	Do.
ANDA 040729	Acetaminophen and Hydrocodone Bitartrate Tablets, 500 mg/5 mg	Do.
ANDA 040304	Acetaminophen and Oxycodone Hydrochloride Capsules, 500 mg/5 mg	Barr Laboratories Inc. 2 Quaker Rd., P.O. Box 2900 Pomona, NY 10956
ANDA 040307	Acetaminophen and Hydrocodone Bitartrate Tablets, 500 mg/2.5 mg Acetaminophen and Hydrocodone Bitartrate Tablets, 500 mg/7.5 mg Acetaminophen and Hydrocodone Bitartrate Tablets, 650 mg/10 mg Acetaminophen and Hydrocodone Bitartrate Tablets, 650 mg/7.5 mg	Do.

ANDA 040308	Acetaminophen and Hydrocodone Bitartrate Tablets, 500 mg/5 mg Acetaminophen and Hydrocodone Bitartrate Tablets, 750 mg/7.5 mg	Do.
ANDA 040309	Acetaminophen and Hydrocodone Bitartrate Tablets, 500 mg/10 mg	Do.
ANDA 040701	Acetaminophen, Caffeine, and Dihydrocodeine Bitartrate Tablets, 712.8 mg/60 mg/32 mg	Boca Pharmacal LLC 3550 Northwest 126th Ave. Coral Springs, FL 33065
ANDA 090265	Acetaminophen and Hydrocodone Bitartrate Tablets, 500 mg/5 mg Acetaminophen and Hydrocodone Bitartrate Tablets, 500 mg/7.5 mg Acetaminophen and Hydrocodone Bitartrate Tablets, 500 mg/10 mg	Caraco Pharmaceutical Laboratories, Ltd. 270 Prospect Plains Rd. Cranbury, NJ 08512
ANDA 090380	Acetaminophen and Hydrocodone Bitartrate Tablets, 650 mg/7.5 mg Acetaminophen and Hydrocodone Bitartrate Tablets, 650 mg/10 mg Acetaminophen and Hydrocodone Bitartrate Tablets, 660 mg/10 mg Acetaminophen and Hydrocodone Bitartrate Tablets, 750 mg/7.5 mg	Do.
ANDA 088898	Acetaminophen and Hydrocodone Bitartrate Capsules, 500 mg/5 mg	Central Pharmaceuticals Inc. 110-128 East 3rd St. Seymour, IN 47274
ANDA 090177	Acetaminophen and Oxycodone Hydrochloride Tablets, 500 mg/7.5 mg Acetaminophen and Oxycodone Hydrochloride Tablets, 650 mg/10 mg	Coastal Pharmaceuticals 1240 Sugg Pkwy. Greenville, NC 27834
ANDA 040289	Acetaminophen and Oxycodone Capsules, 500 mg/5 mg	Duramed Pharmaceuticals Inc. Sub Barr Laboratories Inc. 2 Quaker Rd., P.O. Box 2900 Pomona, NY 10970-0519
ANDA 076202	Acetaminophen and Pentazocine Hydrochloride Tablets, 650 mg/EQ 25 mg Base	Gavis Pharmaceuticals, LLC 400 Campus Dr. Somerset, NJ 08873
ANDA 089696	Acetaminophen and Hydrocodone Bitartrate Tablets, 500 mg/5 mg	Ivax Pharmaceuticals Inc. 140 Legrand Ave. Northvale, NJ 07647
ANDA 089907	ALLAY (Acetaminophen and Hydrocodone Bitartrate) Capsules, 500 mg/5 mg	Do.
ANDA 088790	TYLOX (Acetaminophen and Oxycodone Hydrochloride) Capsules, 500 mg/5 mg	Janssen Research & Development, LLC 920 U.S. Hwy. 202 P.O. Box 300 Raritan, NJ 08869
ANDA 040084	Acetaminophen and Hydrocodone Bitartrate Tablets, 750 mg/7.5 mg Acetaminophen and Hydrocodone Bitartrate Tablets, 500 mg/5 mg Acetaminophen and Hydrocodone Bitartrate Tablets, 650 mg/10 mg Acetaminophen and Hydrocodone Bitartrate Tablets, 660 mg/10 mg	Mallinckrodt Chemical Inc. 675 McDonnell Blvd. Hazelwood, MO 63042

ANDA 040201	Acetaminophen and Hydrocodone Bitartrate Tablets, 500 mg/7.5 mg Acetaminophen and Hydrocodone Bitartrate Tablets, 500 mg/10 mg	Do.
ANDA 040257	Acetaminophen and Oxycodone Hydrochloride Capsules, 500 mg/5 mg	Do.
ANDA 087336	LORCET-HD (Acetaminophen and Hydrocodone Bitartrate) Capsules, 500 mg/5 mg	Do.
ANDA 088956	Acetaminophen and Hydrocodone Bitartrate Capsules, 500 mg/5 mg	Do.
ANDA 088991	BUCET (Acetaminophen and Butalbital) Capsules, 650 mg/50 mg	Do.
ANDA 089006	Acetaminophen and Hydrocodone Bitartrate Capsules, 500 mg/5 mg	Do.
ANDA 089160	ANEXSIA (Acetaminophen and Hydrocodone Bitartrate) Tablets, 500 mg/5 mg	Do.
ANDA 089405	TENCON (Acetaminophen and Butalbital) Capsules, 650 mg/50 mg	Do.
ANDA 089725	ANEXSIA 7.5/650 (Acetaminophen and Hydrocodone Bitartrate) Tablets, 650 mg/7.5 mg	Do.
ANDA 040418	Acetaminophen and Hydrocodone Bitartrate Oral Solution, 500 mg/15 mL; 7.5 mg/15 mL	Do.
ANDA 040468	ANEXSIA (Acetaminophen and Hydrocodone Bitartrate) Tablets, 750 mg/10 mg	Do.
ANDA 040508	Acetaminophen and Hydrocodone Bitartrate Oral Solution, 500 mg/15 mL; 10 mg/15 mL	Do.
ANDA 040550	Acetaminophen and Oxycodone Hydrochloride Tablets, 500 mg/7.5 mg Acetaminophen and Oxycodone Hydrochloride Tablets, 650 mg/10 mg	Do.
ANDA 040085	ESGIC-PLUS (Acetaminophen, Butalbital, and Caffeine) Capsules, 500 mg/50 mg/40 mg	Mikart, Inc. 1750 Chattahoochee Ave. Atlanta, GA 30318
ANDA 040496	Acetaminophen, Butalbital, and Caffeine Tablets, 750 mg/50 mg/40 mg	Do.
ANDA 040676	Acetaminophen and Oxycodone Hydrochloride Tablets, 500 mg/10 mg	Do.
ANDA 040679	Acetaminophen and Oxycodone Hydrochloride Tablets, 400 mg/2.5 mg	Do.
ANDA 040687	Acetaminophen and Oxycodone Hydrochloride Tablets, 400 mg/5 mg	Do.
ANDA 040692	Acetaminophen and Oxycodone Hydrochloride Tablets, 400 mg/10 mg	Do.
ANDA 040698	Acetaminophen and Oxycodone Hydrochloride Tablets, 400 mg/7.5 mg	Do.
ANDA 040849	Acetaminophen and Hydrocodone Bitartrate Tablets, 650 mg/5 mg	Do.

ANDA 081051	Acetaminophen and Hydrocodone Bitartrate Oral Solution, 500 mg/15 mL; 7.5 mg/15 mL	Do.
ANDA 081067	Acetaminophen and Hydrocodone Bitartrate Capsules, 500 mg/5 mg	Do.
ANDA 081223	Acetaminophen and Hydrocodone Bitartrate Tablets, 650 mg/10 mg	Do.
ANDA 089008	Acetaminophen and Hydrocodone Bitartrate Capsules, 500 mg/5 mg	Do.
ANDA 089451	ESGIC-PLUS (Acetaminophen, Butalbital, and Caffeine) Tablets, 500 mg/50 mg/40 mg	Do.
ANDA 089689	Acetaminophen and Hydrocodone Bitartrate Tablets, 650 mg/7.5 mg	Do.
ANDA 089698	Acetaminophen and Hydrocodone Bitartrate Tablets, 500 mg/2.5 mg	Do.
ANDA 089699	Acetaminophen and Hydrocodone Bitartrate Tablets, 500 mg/7.5 mg	Do.
ANDA 089988	BUTAPAP (Acetaminophen and Butalbital) Tablets, 650 mg/50 mg	Do.
ANDA 089231	Acetaminophen and Codeine Phosphate Tablets, 650 mg/30 mg	Do.
ANDA 089271	Acetaminophen and Hydrocodone Bitartrate Tablets, 500 mg/5 mg	Do.
ANDA 089363	Acetaminophen and Codeine Phosphate Tablets, 650 mg/60 mg	Do.
ANDA 040109	Acetaminophen, Caffeine, and Dihydrocodeine Bitartrate Capsules, 356.4 mg/30 mg/16 mg	Do.
ANDA 040316	Acetaminophen, Caffeine, and Dihydrocodeine Bitartrate Tablets, 712.8 mg/60 mg/32 mg	Do.
ANDA 081068	Acetaminophen and Hydrocodone Bitartrate Capsules, 500 mg/5 mg	Do.
ANDA 081069	Acetaminophen and Hydrocodone Bitartrate Capsules, 500 mg/5 mg	Do.
ANDA 081070	Acetaminophen and Hydrocodone Bitartrate Capsules, 500 mg/5 mg	Do.
ANDA 089557	Acetaminophen and Hydrocodone Bitartrate Oral Solution, 500 mg/15 mL; 5 mg/15 mL	Do.
ANDA 089697	Acetaminophen and Hydrocodone Bitartrate Tablets, 500 mg/5 mg	Do.
ANDA 040883	Acetaminophen, Butalbital, and Caffeine Tablets, 500 mg/50 mg/40 mg	Mirror Pharmaceuticals LLC 140 New Dutch Lane Fairfield, NJ 07004
ANDA 040219	Acetaminophen and Oxycodone Capsules, 500 mg/5 mg	Mutual Pharmaceutical Co. Inc. 1100 Orthodox St. Philadelphia, PA 19124
ANDA 040236	Acetaminophen and Hydrocodone Bitartrate Tablets, 500 mg/5 mg Acetaminophen and Hydrocodone Bitartrate Tablets, 750 mg/7.5 mg	Do.

ANDA 040240	Acetaminophen and Hydrocodone Bitartrate Tablets, 650 mg/10 mg Acetaminophen and Hydrocodone Bitartrate Tablets, 650 mg/7.5 mg	Do.
ANDA 040061	ROXILOX (Acetaminophen and Oxycodone Hydrochloride) Capsules, 500 mg/5 mg	Roxane Laboratories Inc. 1809 Wilson Rd. Columbus, OH 43228
ANDA 089775	ROXICET 5/500 (Acetaminophen and Oxycodone Hydrochloride) Tablets, 500 mg/5 mg	Do.
ANDA 040100	LORTAB (Acetaminophen and Hydrocodone Bitartrate) Tablets, 500 mg/10 mg	UCB Inc. 1950 Lake Park Dr., Bldg. 2100 Smyrna, GA 30080
ANDA 087722	LORTAB (Acetaminophen and Hydrocodone Bitartrate) Tablets, 500 mg/5 mg	Do.
ANDA 087757	CO-GESIC (Acetaminophen and Hydrocodone Bitartrate) Tablets, 500 mg/5 mg	Do.
ANDA 088831	PHRENILIN FORTE (Acetaminophen and Butalbital) Capsules, 650 mg/50 mg	Valeant Pharmaceuticals North America LLC 700 Route 202/206 North Bridgewater, NJ 08807
ANDA 040106	Acetaminophen and Oxycodone Hydrochloride Capsules, 500 mg/5 mg	Vintage Pharmaceuticals 150 Vintage Dr. Huntsville, AL 35811
ANDA 040143	Acetaminophen and Hydrocodone Bitartrate Tablets, 650 mg/10 mg	Do.
ANDA 040144	Acetaminophen and Hydrocodone Bitartrate Tablets, 500 mg/2.5 mg Acetaminophen and Hydrocodone Bitartrate Tablets, 500 mg/7.5 mg	Do.
ANDA 040155	Acetaminophen and Hydrocodone Bitartrate Tablets, 650 mg/7.5 mg	Do.
ANDA 040157	Acetaminophen and Hydrocodone Bitartrate Tablets, 750 mg/7.5 mg	Do.
ANDA 040356	Acetaminophen and Hydrocodone Bitartrate Tablets, 500 mg/10 mg	Do.
ANDA 040358	Acetaminophen and Hydrocodone Bitartrate Tablets, 660 mg/10 mg	Do.
ANDA 040513	Acetaminophen, Butalbital, and Caffeine Tablets, 500 mg/50 mg/40 mg	Do.
ANDA 040520	Acetaminophen and Hydrocodone Bitartrate Oral Solution, 500 mg/15 mL; 7.5 mg/15 mL	Do.
ANDA 089971	Acetaminophen and Hydrocodone Bitartrate Tablets, 500 mg/5 mg	Do.
ANDA 089831	Acetaminophen and Hydrocodone Bitartrate Tablets, 500 mg/5 mg	Do.

ANDA 040280	Acetaminophen and Hydrocodone Bitartrate Tablets, 500 mg/7.5 mg Acetaminophen and Hydrocodone Bitartrate Tablets, 650 mg/10 mg Acetaminophen and Hydrocodone Bitartrate Tablets, 650 mg/7.5 mg	Do.
ANDA 040281	Acetaminophen and Hydrocodone Bitartrate Tablets, 500 mg/5 mg Acetaminophen and Hydrocodone Bitartrate Tablets, 750 mg/7.5 mg	Do.
ANDA 040288	ZYDONE (Acetaminophen and Hydrocodone Bitartrate) Tablets, 400 mg/5 mg ZYDONE (Acetaminophen and Hydrocodone Bitartrate) Tablets, 400 mg/7.5 mg ZYDONE (Acetaminophen and Hydrocodone Bitartrate) Tablets, 400 mg/10 mg	Do.
ANDA 040303	Acetaminophen and Oxycodone Hydrochloride Capsules, 500 mg/5 mg	Do.
ANDA 040341	PERCOCET (Acetaminophen and Oxycodone Hydrochloride) Tablets, 500 mg/7.5 mg PERCOCET (Acetaminophen and Oxycodone Hydrochloride) Tablets, 650 mg/10 mg	Do.
ANDA 040371	Acetaminophen and Oxycodone Hydrochloride Tablets, 500 mg/7.5 mg Acetaminophen and Oxycodone Hydrochloride Tablets, 650 mg/10 mg	Watson Laboratories 311 Bonnie Circle Corona, CA 92880
ANDA 040094	Acetaminophen and Hydrocodone Bitartrate Tablets, 650 mg/7.5 mg Acetaminophen and Hydrocodone Bitartrate Tablets, 650 mg/10 mg Acetaminophen and Hydrocodone Bitartrate Tablets, 660 mg/10 mg Acetaminophen and Hydrocodone Bitartrate Tablets, 750 mg/10 mg	Do.
ANDA 040234	Acetaminophen and Oxycodone Hydrochloride Capsules, 500 mg/5 mg	Do.
ANDA 040267	Acetaminophen, Butalbital, and Caffeine Tablets, 500 mg/50 mg/40 mg	Do.
ANDA 081079	Acetaminophen and Hydrocodone Bitartrate Tablets, 500 mg/2.5 mg	Do.
ANDA 081080	Acetaminophen and Hydrocodone Bitartrate Tablets, 500 mg/7.5 mg	Do.
ANDA 081083	Acetaminophen and Hydrocodone Bitartrate Tablets, 750 mg/7.5 mg	Do.
ANDA 040122	Acetaminophen and Hydrocodone Bitartrate Tablets, 500 mg/5 mg Acetaminophen and Hydrocodone Bitartrate Tablets, 750 mg/7.5 mg	Do.

ANDA 040123	Acetaminophen and Hydrocodone Bitartrate Tablets, 650 mg/7.5 mg Acetaminophen and Hydrocodone Bitartrate Tablets, 500 mg/2.5 mg Acetaminophen and Hydrocodone Bitartrate Tablets, 500 mg/7.5 mg Acetaminophen and Hydrocodone Bitartrate Tablets, 650 mg/10 mg	Do.
ANDA 089883	Acetaminophen and Hydrocodone Bitartrate Tablets, 500 mg/5 mg	Do.
ANDA 040493	Acetaminophen and Hydrocodone Bitartrate Tablets, 500 mg/5 mg	Watson Laboratories Inc.-Florida 2945 West Corporate Lakes Blvd., Suite B Weston, FL 33331
ANDA 040494	Acetaminophen and Hydrocodone Bitartrate Tablets, 750 mg/7.5 mg	Do.
ANDA 040495	Acetaminophen and Hydrocodone Bitartrate Tablets, 660 mg/10 mg	Do.
ANDA 040441	CODRIX (Acetaminophen and Codeine Phosphate) Tablets, 500 mg/30 mg	Do.
ANDA 040447	CODRIX (Acetaminophen and Codeine Phosphate) Tablets, 500 mg/15 mg	Do.
ANDA 040488	CODRIX (Acetaminophen and Codeine Phosphate) Tablets, 500 mg/60 mg	Do.
ANDA 040261	Acetaminophen, Butalbital, and Caffeine Capsules, 500 mg/50 mg/40 mg	West-Ward Pharmaceutical Corp. 435 Industrial Way West Eatontown, NJ 07724
ANDA 040336	Acetaminophen, Butalbital, and Caffeine Tablets, 500 mg/50 mg/40 mg	Do.
ANDA 040688	Acetaminophen, Caffeine, and Dihydrocodeine Bitartrate Capsules, 356.4 mg/30 mg/16 mg	WraSer Pharmaceuticals LLC 121 Marketridge Dr. Ridgeland, MS 39157

Therefore, under § 314.150(d), and under authority delegated to the Director, Center for Drug Evaluation and Research, by the Commissioner of Food and Drugs, approval of the applications for the drug products listed in table 1 of this document, and all amendments and supplements thereto, is withdrawn (see DATES). Distribution of these products in interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the FD&C Act (21 U.S.C. 355(a) and 331(d)).

The safety issue discussed in this document and the January 14, 2011, Federal Register document is limited to products containing more than 325 mg of acetaminophen per dosage unit. Thus, the withdrawal of approval of products containing more than 325 mg of acetaminophen per dosage unit listed in table 1 does not change the approval status of any products with 325 mg

or less of acetaminophen per dosage unit that were approved under the same application. In addition, the withdrawal of approval of products containing more than 325 mg of acetaminophen per dosage unit does not change the approval status of products with 325 mg or less of acetaminophen per dosage unit that refer to or rely on the withdrawn products. For example, this withdrawal action will not affect the approval status of an ANDA for a product that contains 325 mg or less per dosage unit that references a product listed in table 1, but for which FDA approved a suitability petition for a lower strength under section 505(j)(2)(C) of the FD&C Act and § 314.93 (21 CFR 314.93)).

Dated: March 24, 2014.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

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