appropriate RLD with an acetaminophen strength at or below 325 mg in the Orange Book. For a small minority of higher acetaminophen strength combinations, there is no approved lower acetaminophen strength product with the same active ingredients that could serve as the RLD. We believe that reformulations of these products, however, could be approved as ANDAs upon approval of an ANDA suitability petition (see section 505(j)(2)(C) of the FD&C Act and § 314.93 (21 CFR 314.93)) permitting the submission of an ANDA for a drug product that is not identical to the RLD in an active ingredient or unit dosage strength, or could be approved as NDAs following submission of applications with appropriate clinical studies.

We are establishing a timeframe for responding to this notice that takes into account the estimated time needed for sponsors to obtain necessary approvals and begin to market new products with lower acetaminophen strengths. We believe that a period of 3 years from publication of this notice in the **Federal Register** will provide adequate time for drug sponsors to prepare to withdraw existing products with higher acetaminophen strengths, and to develop and obtain approval for lower acetaminophen strength versions of those products. We also anticipate that this will provide sufficient time for drug sponsors with approved lower acetaminophen strength products to expand their production to meet the expected increase in demand for lower acetaminophen strength products when the higher strength products become unavailable.

We strongly encourage sponsors of combination prescription products with acetaminophen strengths greater than 325 mg to submit requests for withdrawal of those products' approved applications under § 314.150(d) within the 3-year period described previously. Sponsors who intend to seek approval of one or more new products with acetaminophen strengths of 325 mg or less are encouraged to submit appropriate applications for such products in time to obtain approval within the same period. To that end, we welcome inquiries and requests for consultation from sponsors relating to specific existing or proposed products in connection with this notice. Any such requests from sponsors of currently approved products affected by this notice should be made as correspondence under the affected application(s) and should reference this notice.

We are issuing this notice because we believe that voluntary action on the part of product sponsors to reduce the acetaminophen strengths of prescription acetaminophen combinations can achieve the needed increase in patient safety substantially sooner and with less burden on public and private resources than alternative regulatory measures. However, FDA has authority under section 505(e)(2) of the FD&C Act to withdraw approval of an NDA or ANDA if the Agency determines that the ''* * * drug is not shown to be safe for use under the conditions of use upon the basis of which the drug was approved * * *'' based on consideration of ''* * * new evidence * * * together with the evidence available to [FDA] when the application was approved * * *.'' FDA regulations describe the procedures for withdrawing approval of an application. (See § 314.150 and 21 CFR 314.151, 314.200, 314.201, and 314.235). We intend to use our authority under section 505(e) of the FD&C Act to initiate withdrawal proceedings for any prescription acetaminophen combination products with acetaminophen strengths greater than 325 mg that remain on the market 3 years after the date of publication of this notice.

IV. References

FDA has verified the Web site address in this reference section, but we are not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.

1. FDA Center for Drug Evaluation and Research, Acetaminophen Overdose and Liver Injury—Background and Options for Reducing Injury, Available on FDA's Web site at *http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/DrugSafetyandRiskManagementAdvisoryCommittee/ucm126014.htm.*
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10. Nourjah, P. et al, ''Estimates of Acetaminophen (Paracetamol)-induced Overdoses in the United States,'' Pharacoepidemiological Drug Safety, 6: 406–409, 2006.
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Dated: March 24, 2014.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 2014–06802 Filed 3–26–14; 8:45 am]

BILLING CODE 4160–01–P

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 March 27, 2014.

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.	Do.
	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.	Do.
	Acetaminophen and Hydrocodone Bitartrate Tablets, 500 mg/7.5 mg Acetaminophen and Hydrocodone Bitartrate Tablets, 650 mg/10 mg.	Do.
	Acetaminophen and Hydrocodone Bitartrate Tablets, 650 mg/7.5 mg.	Do.
ANDA 040308	Acetaminophen and Hydrocodone Bitartrate Tablets, 500 mg/5 mg.	Do.
	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.	Do.
	Acetaminophen and Hydrocodone Bitartrate Tablets, 500 mg/7.5 mg.	Do.
	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.	Do.
	Acetaminophen and Hydrocodone Bitartrate Tablets, 650 mg/10 mg.	Do.
	Acetaminophen and Hydrocodone Bitartrate Tablets, 660 mg/10 mg.	Do.
	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.	Do.
	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.

TABLE 1—APPLICATIONS FOR WHICH WITHDRAWAL OF APPROVAL HAS BEEN REQUESTED—Continued

Application No.	Drug product(s)	Applicant or holder
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.	Do.
	Acetaminophen and Hydrocodone Bitartrate Tablets, 500 mg/5 mg.	Do.
	Acetaminophen and Hydrocodone Bitartrate Tablets, 650 mg/10 mg.	Do.
	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.	Do.
	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.	Do.
	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.

TABLE 1—APPLICATIONS FOR WHICH WITHDRAWAL OF APPROVAL HAS BEEN REQUESTED—Continued

Application No.	Drug product(s)	Applicant or holder
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.	Do.
	Acetaminophen and Hydrocodone Bitartrate Tablets, 750 mg/7.5 mg.	Do.
ANDA 040240	Acetaminophen and Hydrocodone Bitartrate Tablets, 650 mg/10 mg.	Do.
	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.	Do.
	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.

TABLE 1—APPLICATIONS FOR WHICH WITHDRAWAL OF APPROVAL HAS BEEN REQUESTED—Continued

Application No.	Drug product(s)	Applicant or holder
ANDA 040280	Acetaminophen and Hydrocodone Bitartrate Tablets, 500 mg/7.5 mg.	Do.
	Acetaminophen and Hydrocodone Bitartrate Tablets, 650 mg/10 mg.	Do.
	Acetaminophen and Hydrocodone Bitartrate Tablets, 650 mg/7.5 mg.	Do.
ANDA 040281	Acetaminophen and Hydrocodone Bitartrate Tablets, 500 mg/5 mg.	Do.
	Acetaminophen and Hydrocodone Bitartrate Tablets, 750 mg/7.5 mg.	Do.
ANDA 040288	ZYDONE (Acetaminophen and Hydrocodone Bitartrate) Tablets, 400 mg/5 mg.	Do.
	ZYDONE (Acetaminophen and Hydrocodone Bitartrate) Tablets, 400 mg/7.5 mg.	Do.
	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.	Do.
	PERCOCET (Acetaminophen and Oxycodone Hydrochloride) Tablets, 650 mg/10 mg.	Do.
ANDA 040371	Acetaminophen and Oxycodone Hydrochloride Tablets, 500 mg/7.5 mg.	Do.
	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.	Do.
	Acetaminophen and Hydrocodone Bitartrate Tablets, 650 mg/10 mg.	Do.
	Acetaminophen and Hydrocodone Bitartrate Tablets, 660 mg/10 mg.	Do.
	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.	Do.
	Acetaminophen and Hydrocodone Bitartrate Tablets, 750 mg/7.5 mg.	Do.
ANDA 040123	Acetaminophen and Hydrocodone Bitartrate Tablets, 650 mg/7.5 mg.	Do.
	Acetaminophen and Hydrocodone Bitartrate Tablets, 500 mg/2.5 mg.	Do.
	Acetaminophen and Hydrocodone Bitartrate Tablets, 500 mg/7.5 mg.	Do.
	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.

TABLE 1—APPLICATIONS FOR WHICH WITHDRAWAL OF APPROVAL HAS BEEN REQUESTED—Continued

Application No.	Drug product(s)	Applicant or holder
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.

[FR Doc. 2014–06801 Filed 3–26–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Vaccine Injury Compensation Program; List of Petitions Received

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) is publishing this notice of petitions received under the National Vaccine Injury Compensation Program (the Program), as required by Section 2112(b)(2) of the Public Health Service (PHS) Act, as amended. While the Secretary of Health and Human Services is named as the respondent in all proceedings brought by the filing of petitions for compensation under the Program, the United States Court of Federal Claims is charged by statute with responsibility for considering and acting upon the petitions.

FOR FURTHER INFORMATION CONTACT: For information about requirements for filing petitions, and the Program in general, contact the Clerk, United States Court of Federal Claims, 717 Madison Place NW., Washington, DC 20005, (202) 357–6400. For information on HRSA's role in the Program, contact the Director, National Vaccine Injury Compensation Program, 5600 Fishers Lane, Room 11C–26, Rockville, MD 20857; (301) 443–6593.

SUPPLEMENTARY INFORMATION: The Program provides a system of no-fault compensation for certain individuals who have been injured by specified childhood vaccines. Subtitle 2 of Title XXI of the PHS Act, 42 U.S.C. 300aa-10 *et seq.,* provides that those seeking compensation are to file a petition with the U.S. Court of Federal Claims and to serve a copy of the petition on the Secretary of Health and Human Services, who is named as the respondent in each proceeding. The Secretary has delegated this responsibility under the Program to HRSA. The Court is directed by statute to appoint special masters who take evidence, conduct hearings as appropriate, and make initial decisions as to eligibility for, and amount of, compensation.

A petition may be filed with respect to injuries, disabilities, illnesses, conditions, and deaths resulting from vaccines described in the Vaccine Injury Table (the Table) set forth at Section 2114 of the PHS Act or as set forth at 42 CFR 100.3, as applicable. This Table lists for each covered childhood vaccine the conditions which may lead to compensation and, for each condition, the time period for occurrence of the first symptom or manifestation of onset or of significant aggravation after vaccine administration. Compensation may also be awarded for conditions not listed in the Table and for conditions that are manifested outside the time periods specified in the Table, but only if the petitioner shows that the condition was caused by one of the listed vaccines.

Section 2112(b)(2) of the PHS Act, 42 U.S.C. 300aa–12(b)(2), requires that ''[w]ithin 30 days after the Secretary receives service of any petition filed under section 2111 the Secretary shall publish notice of such petition in the **Federal Register**.'' Set forth below is a list of petitions received by HRSA on February 1, 2014, through February 28, 2014. This list provides the name of petitioner, city and state of vaccination (if unknown then city and state of person or attorney filing claim), and case number. In cases where the Court has redacted the name of a petitioner and/or the case number, the list reflects such redaction.

Section 2112(b)(2) also provides that the special master ''shall afford all interested persons an opportunity to submit relevant, written information'' relating to the following:

1. The existence of evidence ''that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition,'' and

2. Any allegation in a petition that the petitioner either:

(a) ''Sustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Vaccine Injury Table but which was