

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[CDC–2013–0022; Docket Number NIOSH–153–B]

Issuance of Final Guidance Publications

AGENCY: National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of issuance of final guidance publications.

SUMMARY: The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), announces the availability of the following 15 *Skin Notation Profiles* [DHHS (NIOSH) Publication Nos. 2015–191 to 2015–195 and 2015–226 to 2015–235]:

Substance(s)

Aldrin: http://www.cdc.gov/niosh/docs/2015-191/pdfs/f15_snp_aldrin_2015-191.pdf.

Aniline: http://www.cdc.gov/niosh/docs/2015-192/pdfs/f15_snp_aniline_2015-192.pdf.

Azinphos-methyl: http://www.cdc.gov/niosh/docs/2015-235/pdfs/f15_snp_2015-235.pdf.

Captafol: http://www.cdc.gov/niosh/docs/2015-193/pdfs/f15_snp_captafol_2015-193.pdf.

Chlordane: http://www.cdc.gov/niosh/docs/2015-229/pdfs/f15_snp_2015-229.pdf.

Dieldrin: http://www.cdc.gov/niosh/docs/2015-229/pdfs/f15_snp_2015-229.pdf.

Dinitro-o-cresol: http://www.cdc.gov/niosh/docs/2015-195/pdfs/f15_snp_dinitro-o-cresol_2015-195.pdf.

Endrin: http://www.cdc.gov/niosh/docs/2015-233/pdfs/f15_snp_2015-233.pdf.

Methyl parathion: http://www.cdc.gov/niosh/docs/2015-231/pdfs/f15_snp_2015-231.pdf.

Nicotine: http://www.cdc.gov/niosh/docs/2015-234/pdfs/f15_snp_2015-234.pdf.

Parathion: http://www.cdc.gov/niosh/docs/2015-232/pdfs/f15_snp_2015-232.pdf.

Phorate: http://www.cdc.gov/niosh/docs/2015-230/pdfs/f15_snp_2015-230.pdf.

Phosdrin: http://www.cdc.gov/niosh/docs/2015-226/pdfs/f15_snp_2015-226.pdf.

Tetraethyl dithionopyrophosphate (TEDP): http://www.cdc.gov/niosh/docs/2015-227/pdfs/f15_snp_2015-227.pdf.

Tetraethyl pyrophosphate (TEPP): http://www.cdc.gov/niosh/docs/2015-228/pdfs/f15_snp_2015-228.pdf.

ADDRESSES: These documents may be obtained at the following link: http://www.cdc.gov/niosh/topics/skin/skin-notation_profiles.html.

FOR FURTHER INFORMATION CONTACT: Naomi Hudson, NIOSH, Robert A. Taft Laboratories, 1090 Tusculum Avenue, MS C–32, Cincinnati, OH 45226. (513) 533–8388 (not a toll free number). Email: iuz8@cdc.gov.

Dated: October 5, 2015.

John Howard,
Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

[FR Doc. 2015–25974 Filed 10–9–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Title IV–E Plan for Foster Care, Adoption Assistance, and, optional, Guardianship Assistance Programs.

OMB No.: 0970–0433.

Description: A title IV–E plan is required by section 471, part IV–E of the Social Security Act (the Act) for each public child welfare agency requesting Federal funding for foster care, adoption assistance and guardianship assistance under the Act. Section 479B of the Act provides for an Indian tribe, tribal organization or tribal consortium (Tribe) to operate a title IV–E program in the same manner as a State with minimal exceptions. The Tribe must have an approved title IV–E Plan. The title IV–E plan provides assurances the programs will be administered in conformity with the specific requirements stipulated in title IV–E. The plan must include all applicable State or Tribal statutory, regulatory, or policy references and citations for each requirement as well as supporting documentation. A title IV–E agency may use the pre-print format prepared by the Children’s Bureau of the Administration for Children and Families or a different format, on the condition that the format used includes all of the title IV–E plan requirements of the law.

Respondents: Title IV–E agencies administering or supervising the administration of the title IV–E programs.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Title IV–E Plan	17	1	16	272

Estimated Total Annual Burden Hours: 272.

Additional Information

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L’Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title

of the information collection. Email address: infocollection@acf.hhs.gov.

OMB Comment

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and

recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: OIRA_SUBMISSION@OMB.EOP.GOV. Attn:

Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2015-25924 Filed 10-9-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-3432]

Organon USA Inc. et al.; Withdrawal of Approval of 67 New Drug Applications and 128 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 67 new drug applications (NDAs) and 128 abbreviated new drug applications (ANDAs) from multiple applicants. The holders of the applications notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: *Effective Date:* November 12, 2015.

FOR FURTHER INFORMATION CONTACT:

Florine P. Purdie, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6248,

Silver Spring, MD 20993-0002, 301-796-3601.

SUPPLEMENTARY INFORMATION: The holders of the applications listed in table 1 in this document have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

TABLE 1

Application No.	Drug	Applicant
NDA 001104	Doca (desoxycorticosterone acetate) Injection, 5 milligrams (mg)/milliliter (mL).	Organon USA Inc., Subsidiary of Merck Sharp & Dohme Corp., 2000 Galloping Hill Rd., Kenilworth, NJ 07033.
NDA 004589	Alcohol in Dextrose Injection USP, 10 mL/100 mL and 5 grams (g)/100 mL.	B. Braun Medical Inc., 901 Marcon Blvd., Allentown, PA 18109.
NDA 006170	Hyprotigen (modified protein hydrolysate) Injection, 5%	Do.
NDA 012154	Ureaphil (urea) for Injection, 40 g/vial	Hospira, Inc., 275 North Field Dr., Lake Forest, IL 60045.
NDA 012449	Oratrol (dichlorophenamide) Tablets, 50 mg	Alcon Laboratories Inc., 6201 South Freeway, P.O. Box 1959, Fort Worth, TX 76134.
NDA 012699	Lomotil (atropine sulfate and diphenoxylate hydrochloride (HCl)) Solution 0.025 mg/5 mL and 2.5 mg/5 mL.	G.D. Searle, LLC, 235 East 42nd St., New York, NY 10017.
NDA 012892	Uracil Mustard Capsule	Shire Development Inc., 725 Chesterbrook Blvd., Wayne, PA 19087-5637.
NDA 014738	Mannitol Injection USP, 20%	B. Braun Medical Inc.
NDA 016080	Mannitol Injection USP	Do.
NDA 016096	Mintezol (thiabendazole) Tablets	Merck Sharp & Dohme Corp., 1 Merck Drive, P.O. Box 100, Whitehouse Station, NJ 08889.
NDA 016097	Mintezol (thiabendazole) Oral Suspension	Do.
NDA 016695	Dextrose Injection, 5% (in Ringer's)	Baxter Healthcare Corp. 32650 N. Wilson Rd., Round Lake, IL 60073.
NDA 017390	Plasma-Lyte M and Dextrose 5% Injection	Do.
NDA 017438	Plasma-Lyte R Injection	Do.
NDA 017451	Plasma Lyte 148 and Dextrose 5% Injection	Do.
NDA 017493	Travasol (amino acids) Injection, 10%	Do.
NDA 017510	Dextrose 5% Injection (in lactated Ringer's)	B. Braun Medical Inc.
NDA 017636	Sorbitol-Mannitol Irrigation, 2.7 g/100 mL-540 mg/100 mL ..	Hospira, Inc.
NDA 017698	Serile Urea Injection	Do.
NDA 017911	Clinoril (sulindac) Tablets, 150 mg and 200 mg	Merck Sharp & Dohme Corp.
NDA 017957	Novamine (amino acids) Injection	Hospira, Inc.
NDA 017995	Dextrose Injection USP, 60%	B. Braun Medical Inc.
NDA 018191	Drixoral Non-Drowsy (pseudoephedrine sulfate) Extended-Release Tablets, 120 mg.	MSD Consumer Care, Inc., 556 Morris Ave., Summit, NJ 07901.
NDA 018242	Sulfamethoxazole and Trimethorim Tablets USP	Teva Pharmaceuticals USA, 425 Privet Rd., Horsham, PA 19044.
NDA 018258	Dextrose Injection 5% (in acetated Ringer's)	B. Braun Medical Inc.
NDA 018268	Dextrose, Sodium Chloride, and Potassium Chloride Injection USP, 5%.	Do.
NDA 018307	Thyro-Block (potassium iodide tablets USP)	Meda Pharmaceuticals Inc., 265 Davidson Ave., Suite 400, Somerset, NJ 08873.
NDA 018308	Thyro-Block (potassium iodide solution), 21 mg	Do.
NDA 018312	Calderol (calcifediol) Capsules	Organon USA Inc., Subsidiary of Merck & Co., Inc.
NDA 018376	Dextrose and Sodium Chloride Injection, 2.5%/0.9%	B. Braun Medical Inc.
NDA 018531	Nitroglycerin Injection USP, 5 mg/mL	Hospira, Inc.
NDA 018533	Nizoral (ketoconazole) Tablets, 200 mg	Janssen Pharmaceuticals, Inc., c/o Janssen Research & Development, LLC, 920 Route 202 South, P.O. Box 300, Raritan, NJ 08869-0602.
NDA 018684	Branchamin (amino acids) Injection, 4%	Baxter Healthcare Corp.
NDA 018722	Sodium Chloride 0.9%, and Potassium Chloride Injection ...	B. Braun Medical Inc.
NDA 018725	Acetated Ringer's Injection	Do.