''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration (CDER), 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002, or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Norman R. Schmuff, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, Rm. 2526, Silver Spring, MD 20993–0002, *Norman.Schmuff@fda.hhs.gov;* or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911. *Regarding the ICH:* Amanda Roache, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1176, Silver Spring, MD 20993–0002, 301–796–4548.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically-based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products for human use among regulators around the world. The six founding members of the ICH are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; CDER and CBER, FDA; and the Pharmaceutical Research and Manufacturers of America. The Standing Members of the ICH Association include Health Canada and Swissmedic. Any party eligible as a member in accordance with the ICH Articles of Association can apply for membership in writing to the ICH Secretariat. The ICH Secretariat, which coordinates the preparation of documentation, operates as an international nonprofit organization and is funded by the members of the ICH Association.

The ICH Assembly is the overarching body of the Association and includes representatives from each of the ICH members and observers.

The M4 guidance provides guidance on the organization of the CTD and eCTD for Modules 2 through 5 providing direction on the location and hierarchy of headings within modules, document pagination and segregation, section numbering within documents, and the formatting of the table of contents. The guidance updates the Quality-related sections of the Granularity Document Annex, Module 2.3 Quality Overall Summary, and Module 3 Quality. The guidance provides separate tables describing the recommended granularity for paper and eCTD v3.2.2 submissions, and for paper and eCTD v4 submissions, and includes ''Appendices for eCTD v4 Submissions'' to facilitate the implementation of the next major version of the eCTD. This guidance replaces both the August 2001 FDA GIF ''M4: Organization of the CTD'' and the October 2005 FDA GIF ''Granularity Document Annex to M4: Organization of the CTD.'' This merger reflects the 2002 addition of the Annex: Granularity Document into the ''M4 Organization of the Common Technical Document for the Registration of Pharmaceuticals for Human Use.''

There have been no updates or changes relative to Module 4 or Module 5.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on the organization of the CTD for the registration of pharmaceuticals for human use. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons with access to the internet may obtain the document at *https://www.regulations.gov, https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm,* or *https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.*

Dated: September 28, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–21229 Filed 10–2–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–4563]

Johnson & Johnson Consumer Inc. et al.; Withdrawal of Approval of 7 New Drug Applications and 71 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 7 new drug applications (NDAs) and 71 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: Withdrawal of approval is effective November 2, 2017.

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 the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications pursuant to 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.

Application No.	Drug	Applicant
NDA 014349	Delfen (nonoxynol-9) Contraceptive Foam, 12.5%	Johnson & Johnson Consumer Inc., 199 Grandview Rd., Skillman, NJ 08558.
ANDA 019346	Dextrose 60% Injection USP in Plastic Container	Hospira, Inc., 275 North Field Dr., Dept. 389, Bldg. H2–2, Lake Forest, IL 60045.
NDA 019810	Prilosec (omeprazole) Delayed-Release Capsules, 10 milligrams (mg), 20 mg, and 40 mg.	AstraZeneca Pharmaceuticals LP, One MedImmune Way, Gaithersburg, MD 20878.
NDA 020184	Aceon (perindopril erbumine) Tablets, 2 mg, 4 mg, and 8 mg.	Symplmed Pharmaceuticals, LLC, 5375 Medspace Way, Cincinnati, OH 45227.
NDA 022345	Potiga (ezogabine) Tablets, 50 mg, 200 mg, 300 mg, and 400 mg.	GlaxoSmithKline Intellectual Property Management LTD England, c/o GlaxoSmithKline, 1250 South Collegeville Road, P.O. Box 5089, Collegeville, PA 19426.
NDA 021712	Fluxid (famotidine) Orally Disintegrating Tablets, 20 mg and 40 mg.	UCB, Inc., 1950 Lake Park Dr., Bldg. 2100, Smyrna, GA 30080.
ANDA 040108	Acetazolamide for Injection USP, Equivalent to (EQ) 500 mg base/vial.	Hospira, Inc.
ANDA 040206	Digoxin Injection USP, 0.25 mg/milliliter (mL)	Do.
ANDA 040527	Phentermine Hydrochloride (HCl) Capsules USP, 37.5 mg	Sun Pharmaceutical Industries, Inc., 270 Prospect Plains Rd., Cranbury, NJ 08512.
ANDA 040899	Hydroxyzine HCl Tablets USP, 10 mg, 25 mg, and 50 mg	Do.
ANDA 060099	Penicillin G Procaine for Injection, 300,000 units/vial and 1,500,000 units/vial.	Pfizer Inc., 235 East 42nd St., New York, NY 10017.
ANDA 063161	Tobramycin Injection USP, EQ 40 mg base/mL	Hospira, Inc.
ANDA 070171	Naloxone HCl Injection USP, 0.02 mg/mL	Do.
ANDA 070186	Disopyramide Phosphate Capsules USP, EQ 100 mg base.	Ivax Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.
ANDA 070233	Propranolol HCl Tablets USP, 20 mg	Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.
ANDA 070255	Naloxone HCl Injection, 0.4 mg/mL	Hospira, Inc.
ANDA 070698	Methyldopate HCl Injection USP, 50 mg/mL, ADD-Vantage Vial.	Do.
ANDA 070699	Methyldopate HCl Injection USP, 50 mg/mL, Fliptop Vial	Do.
ANDA 070739	Verapamil HCl Injection, 2.5 mg/mL, 2 mL Abbojet-PA Syringe.	Do.
ANDA 070740	Verapamil HCl Injection, 2.5 mg/mL, 4 mL Abbojet Syringe Vial.	Do.
ANDA 070803	Enflurane USP, 99.9%	Abbott Laboratories, Hospital Products Division, 200 Abbott Park Rd., D389, Bldg. J45–2, Abbott Park, IL 60064.
ANDA 070888	Aminocaproic Acid Injection USP, 250 mg/mL	Hospira, Inc.
ANDA 071357	Tolazamide Tablets USP, 100 mg	Sun Pharmaceutical Industries, Inc.
ANDA 071438	Ritodrine HCl in Dextrose 5% Injection, 30 mg/100 mL	Hospira, Inc.
ANDA 071618	Ritodrine HCl Injection USP, 10 mg/mL	Do.
ANDA 071619	Ritodrine HCl Injection USP, 15 mg/mL	Do.
ANDA 071982	Droperidol and Fentanyl Citrate Injection, 2.5 mg/mL and EQ 0.05 mg base/mL.	Do.
ANDA 072321	Pancuronium Bromide Injection, 2 mg/mL	Do.
ANDA 073199	Sulfamethoxazole and Trimethoprim Injection USP, 80 mg/mL and 16 mg/mL.	Do.
ANDA 073310	Tolmetin Sodium Tablets USP, EQ 200 mg base	Sun Pharmaceutical Industries, Inc.
ANDA 073428	CO–LAV (polyethylene glycol 3350 and electrolytes) for Oral Suspension.	Vintage Pharmaceuticals, 150 Vintage Dr., Huntsville, AL 35811.
ANDA 073433	GO–EVAC (polyethylene glycol 3350 and electrolytes) for Oral Suspension.	Do.
ANDA 073677	Carbastat (carbachol) Intraocular Solution, 0.01%	Novartis Pharmaceuticals Corp., One Health Plaza, East Hanover, NJ 07936.
ANDA 074168	Diltiazem HCl Tablets USP, 30 mg, 60 mg, 90 mg, and 120 mg.	Ivax Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 074280	Lorazepam Injection USP, 2 mg/mL and 4 mg/mL	Hospira, Inc.
ANDA 074296	Cimetidine HCl Injection, EQ 300 mg base/2 mL (Carpuject).	Do.
ANDA 074412	Cimetidine HCl Injection, EQ 300 mg base/2 mL	Do.
ANDA 074422	Cimetidine HCl Injection, EQ 300 mg base/2 mL, ADD-Vantage Vial.	Do.
ANDA 074468	Cimetidine HCl in Sodium Chloride 0.9% Injection in Plastic Container, EQ 90 mg base/100 mL, EQ 120 mg base/100 mL, EQ 180 mg base/100 mL, EQ 240 mg base/100 mL, EQ 360 mg/100 mL, and EQ 480 mg base/100 mL.	Do.
ANDA 074620	Butorphanol Tartrate Injection USP, 1 mg/mL and 2 mg/mL.	Do.
ANDA 074758	Acyclovir for Injection USP, EQ 500 mg base/vial and EQ 1 gram (g) base/vial.	Do.

Application No.	Drug	Applicant
ANDA 074801	Ketorolac Tromethamine Injection USP, 15 mg/mL and 30 mg/mL.	Do.
ANDA 075385	Buspirone HCl Tablets USP, 5 mg, 10 mg, and 15 mg	Ivax Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 075453	Doxazosin Tablets USP, EQ 1 mg base, EQ 2 mg base, EQ 4 mg base, and EQ 8 mg base.	Do.
ANDA 076883	Sotalol HCl Tablets USP, 80 mg, 120 mg, and 160 mg	Teva Pharmaceuticals USA, Inc.
ANDA 077052	Citalopram Hydrobromide Tablets, EQ 10 mg base, EQ 20 mg base, and EQ 40 mg base.	Sun Pharmaceutical Industries, Inc.
ANDA 077937	Meloxicam Tablets, 7.5 mg and 15 mg	Do.
ANDA 078081	Amlodipine Besylate Tablets, EQ 2.5 mg base, EQ 5 mg base, and EQ 10 mg base.	Do.
ANDA 078158	Fosphenytoin Sodium Injection USP, EQ 50 mg Phenytoin Soudium/mL.	Hospira, Inc.
ANDA 078483	Zolpidem Tartrate Extended-Release Tablets USP, 6.25 mg and 12.5 mg.	Synthon Pharmaceuticals, Inc., 1007 Slater Rd., Suite 150, Durham, NC 27703.
ANDA 080136	Isoniazid Tablets, 100 mg	Sun Pharmaceutical Industries, Inc.
ANDA 080209	Prednisone Tablets USP, 5 mg	Contract Pharmacal Corp., c/o SciRegs International Inc., 6333 Summercrest Dr., Columbia, MD 21045.
ANDA 080224	Sorbitol; Mannitol Irrigation Solution, 2.7 g/100 mL; 540 mg/100 mL.	Hospira, Inc.
ANDA 083345	Potassium Chloride for Injection Concentrate USP, 1 milliequivalent (mEQ)/mL, 1.5 mEQ/mL, and 2 mEQ/mL.	Do.
ANDA 083808	Quinidine Sulfate Tablets USP, 200 mg	Contract Pharmacal Corp., c/o SciRegs International Inc.
ANDA 084623	Chlordiazepoxide HCl Capsules USP, 10 mg	Upsher-Smith Laboratories, Inc., 6701 Evenstad Dr., Maple Grove, MN 55369.
ANDA 084644	Chlordiazepoxide HCl Capsules USP, 5 mg	Do.
ANDA 084710	Ogen (estropipate) Vaginal Cream USP, 1.5 mg/g	Pfizer Inc.
ANDA 085061	Folic Acid Tablets USP, 1 mg	Contract Pharmacal Corp., c/o SciRegs International Inc.
ANDA 085933	Phentermine HCl Tablets USP	Lemmon Co., 650 Cathill Rd., Sellersville, PA 18960.
ANDA 086494	Chlordiazepoxide HCl Capsules, 25 mg	Teva Pharmaceuticals USA, Inc.
ANDA 086821	Hydroxyzine HCl Injection USP, 50 mg/mL	Hospira, Inc.
ANDA 087416	Hydroxyzine HCl Injection USP, 25 mg/mL, Carpuject	Do.
ANDA 087546	Hydroxyzine HCl Injection USP, 50 mg/mL, Carpuject	Do.
ANDA 087862	Hydroxyzine HCl Tablets USP, 100 mg	Sun Pharmaceutical Industries, Inc.
ANDA 088147	Aminophylline in Sodium Chloride 0.45% Injection, 100 mg/100 mL and 200 mg/100 mL.	Hospira, Inc.
ANDA 088367	Lidocaine HCl Injection USP, 10%	Do.
ANDA 088542	Lidocaine HCl Injection USP, 4%	Do.
ANDA 089162	Cyclopentolate HCl Ophthalmic Solution, 1%	Alcon Pharmaceuticals, Ltd., 6201 South Freeway TC–45, Fort Worth, TX 76134.
ANDA 089347	Diatrizoate Meglumine and Diatrizoate Sodium Injection USP, 66%; 10%.	Bracco Diagnostics Inc., 259 Prospect Plains Rd., Bldg. H, Monroe Township, NJ 08831.
ANDA 089393	Glycopyrrolate Injection USP, 0.2 mg/mL	Hospira, Inc.
ANDA 089488	Diphenhydramine HCl Capsules, 25 mg	Sun Pharmaceutical Industries, Inc.
ANDA 089521	Phenytoin Sodium Injection USP, 50 mg/mL, Ampule	Hospira, Inc.
ANDA 089537	Procainamide HCl Injection USP, 500 mg/mL, Carpuject	Do.
ANDA 089744	Phenytoin Sodium Injection USP, 50 mg/mL, Carpuject	Do.
ANDA 089915	Leucovorin Calcium for Injection, EQ 100 mg base/vial	Pharmachemie B.V., c/o SICOR Pharmaceuticals, Inc., 19 Hughes, Irvine, CA 92618.
NDA 202258	Victrelis (boceprevir) Capsules, 200 mg	Merck Sharp & Dohme Corp., Subsidiary of Merck & Company, Inc., 1 Merck Dr., P.O. Box 100, Whitehouse Station, NJ 08889.
NDA 203093	Vitekta (elvitegravir) Tablets, 85 mg and 150 mg	Gilead Sciences, Inc., 333 Lakeside Dr., Foster City, CA 94404.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn, effective November 2, 2017. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on the date that this notice becomes effective (see **DATES**) may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: September 27, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–21177 Filed 10–2–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–4977]

Joint Meeting of the Psychopharmacologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) announces a forthcoming public