TABLE 1—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE FROM JANUARY 1, 2012, THROUGH MARCH 31, 2012—Continued

PMA No., Docket No.	Applicant	Trade name	Approval date
P060008.S046, FDA–2012–M–0210 ...	Boston Scientific Corp	TAXUS Liberté Paclitaxel-Eluting Coronary Stent System (Monorail and Over-The-Wire Delivery Systems).	February 22, 2012.
P030025.S086, FDA–2012–M–0209 ...	Boston Scientific Corp	TAXUS Express2 Paclitaxel-Eluting Coronary Stent System (Monorail and Over-The-Wire Delivery Systems).	February 22, 2012.
P110023, FDA–2012–M–0221	ev3, Inc	Everflex Self-Expanding Peripheral Stent System (Everflex).	March 7, 2012.
P070004, FDA–2012–M–0250	Sientra, Inc	SIENTRA Silicone Gel Breast Implants.	March 9, 2012.

II. Electronic Access

Persons with access to the Internet may obtain the documents at *http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/default.htm* and *http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/HDEApprovals/ucm161827.htm.*

Dated: June 8, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–14486 Filed 6–13–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0001]

Update to Electronic Common Technical Document Module 1

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

The Food and Drug Administration (FDA) is announcing the following meeting: Update to Electronic Common Technical Document Module 1. The topic to be discussed is final documentation of the Electronic Common Technical Document (eCTD) Module 1, which is used for electronic submission of administrative and prescribing information by industry. The purpose of the meeting is to provide clarification and answer questions from industry and software vendors regarding the changes being made to this module. Registration is required in advance and participation will be limited.

DATES: *Date and Time:* The meeting will be held on Tuesday, September 18, 2012, from 8 a.m. to 11:30 a.m.

LOCATION: The meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, Great Room 1503, Silver Spring, MD 20993. The following link contains public meeting attendee information as well as frequently asked questions and answers regarding public meetings at White Oak: *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

CONTACT: Julie Quinonez, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 1135, Silver Spring, MD 20993, 301–796–0282, FAX: 301–796–9876, email: *Julie.Quinonez@fda.hhs.gov.*

Registration: Send registration information (including name, title, firm name, address, telephone, and fax number) to Julie Quinonez (see *Contact*). Registrations will be accepted in the order that they are received with a limit of 350.

SUPPLEMENTARY INFORMATION: The eCTD is an International Conference on Harmonization (ICH) standard based on specifications developed by ICH and its member parties. The Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) have been receiving submissions in the eCTD format since 2003, and the eCTD has been the standard for electronic submissions to CDER and CBER since January 1, 2008. In fact, the majority of new electronic submissions are now received in eCTD format. Since adoption of the eCTD standard, it has become necessary to update the administrative portion of the eCTD Module 1 to reflect regulatory changes; to provide clarification of business rules for submission, processing, and review; to refine the characterization of promotional labeling and advertising material; and to facilitate automated processing of submissions. In the process of considering these changes, FDA has previously made available for comment versions of documents that support making regulatory submissions in electronic format using the (eCTD) specifications. These draft documents represented FDA's major updates to Module 1 of the eCTD based on previous comments. FDA will make available revised versions of these documents in preparation for this meeting. These documents will be posted at: *http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm253101.htm.*

If you need special accommodations due to a disability, please contact Julie Quinonez (see *Contact*) at least 7 days in advance.

Dated: June 8, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–14469 Filed 6–13–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0517]

Notice of Withdrawal of Certain Unapproved Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing its intention to deem to be withdrawn any abbreviated new drug applications (ANDAs) that have been determined to be incomplete and as to which the ANDA applicant has not communicated with FDA since July 8, 1991. Each of these applications will be

deemed to have been withdrawn voluntarily by the applicant unless the applicant informs the Agency in writing that it intends to actively pursue approval of the application(s) (see **DATES**).

DATES: The applicant of an ANDA covered by this notice that intends to actively pursue approval of its application must submit a written notification to FDA by August 13, 2012.

ADDRESSES: Applicants should submit written notifications to the ANDA archival file to the Office of Generic Drugs, Center for Drug Evaluation and Research, Food and Drug Administration, Document Control Room, MPN7, 7620 Standish Pl., Rockville, MD 20855. A copy of written notifications should also be submitted to Thomas Hinchliffe, Center for Drug Evaluation and Research (HFD–617), Food and Drug Administration, 7500 Standish Pl., rm. N–142, MPN2, Rockville, MD 20855, FAX: 240–276–8440, email: *inactiveandas@fda.hhs.gov.*

FOR FURTHER INFORMATION CONTACT: Thomas Hinchliffe, Center for Drug Evaluation and Research (HFD–617), Food and Drug Administration, 7500 Standish Pl., rm. N–142, MPN2, Rockville, MD 20855, 240–276–8433, FAX: 240–276–9310, *email: inactiveandas@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA has identified 364 ANDAs for which FDA has not received any communication from the ANDA applicant since July 8, 1991, or earlier (Inactive ANDAs). (See section IV of this document for the list of Inactive ANDAs). For purposes of this document, the term ''applicant'' includes any successor in interest. FDA's regulations provide that the Agency will consider withdrawn any application for which the applicant has not contacted the Agency about its intention regarding such application within 1 year after issuance of a complete response letter to the applicant (see 21 CFR 314.110(c)). The Inactive ANDAs, however, predate, and consequently are not subject to this regulation. Therefore, the Inactive ANDAs have not been deemed withdrawn although there has been no communication from the applicants since July 8, 1991, or earlier.

II. Withdrawal of Inactive ANDAs

At this time, the Agency is announcing its intention to deem all Inactive ANDAs to have been voluntarily withdrawn by the respective applicants as of August 13, 2012, unless the applicant informs the Agency in writing by the date set forth under **DATES** in this document of its intent to actively pursue approval of the application. Therefore, in the absence of a written notice with respect to an Inactive ANDA by the date specified in this notice, the ANDA will be considered to have been withdrawn by the applicant. No further notice of the withdrawal of Inactive ANDAs will be provided. Withdrawal of an unapproved application is without prejudice to resubmission of that application (21 CFR 314.65). Because of the length of time that has passed since these applications were submitted, FDA strongly recommends that any applicant intending to actively pursue approval review the application carefully to determine whether it satisfies current ANDA requirements (21 CFR part 314).

III. Action by the Applicant

If the applicant wishes to actively pursue approval of an Inactive ANDA and does not wish the application to be deemed by FDA to have been voluntarily withdrawn, the applicant must inform the Agency in writing within the time specified in this document. Written notice should be provided to Thomas Hinchliffe and the Office of Generic Drugs (see **ADDRESSES**).

FDA also asks any applicant that agrees to consider its application to be voluntarily withdrawn to send a written notice to Thomas Hinchliffe and the Office of Generic Drugs (see **ADDRESSES**) to confirm that agreement. However, applicants of Inactive ANDAs covered by this notice who wish their applications to be withdrawn are not required to provide written notice to FDA.

IV. Details About Inactive ANDAs

Information about the Inactive ANDAs is listed in this section of the document. To protect applicant confidentiality, this notice lists the application number and drug name for each Inactive ANDA and separately lists the name of the applicant as shown in the information on file with FDA, without linking identified applicants with specific applications or drug names. In some cases, the identified applicants may no longer exist as ongoing business entities. If an identified applicant is unsure which application(s) belong to it (if any), it may contact Thomas Hinchliffe (see **FOR FURTHER INFORMATION CONTACT**).

Alphabetical List of Abbreviated New Drug Application Applicants

1st Texas Pharmaceuticals, Inc., Subsidiary of Scherer Laboratories Inc.
Abraxis Pharmaceutical Products
AH Robins, Co.
Alpharma US Pharmaceuticals Division
Ambix Laboratories Division of Organics Corp America
Ankerfarm SpA
Ankerman SpA
Antibioticos SA
Arcum Pharmaceutical Corp.
Banner Pharmacaps, Inc.
Barr Laboratories, Inc.
Baxter Healthcare Corp.
Beecham Laboratories Division of Beecham Inc.
Beecham SA
Bel Mar Laboratories, Inc.
Biocraft Laboratories, Inc.
Biometric Testing, Inc.
Boots Laboratories, Inc., Division of Boots Pharmaceuticals Inc.
Bristol Laboratories, Inc., Division of Bristol Myers Co.
Bristol Myers Co. International Division
Bristol Myers Industrial Division
Bristol Myers Squibb
Camall Co., Inc.
Carlo Erba SpA
Century Pharmaceuticals, Inc.
Chemibiotic Ireland, Ltd.
Chromalloy Laboratories Division of Chromalloy Pharmaceuticals, Inc.
Clifford Chemical Corp.
CM Bundy Co.
Comatic Laboratories, Inc.
Credo Co.
Delco Chemical Co., Inc.
Dell Laboratories, Inc.
Dermasave Laboratories, Inc.
Dista Products Co. Division of Eli Lilly & Co.
DM Pharmaceuticals, Inc.
Dorasol Laboratories
Dunhall Pharmaceuticals, Inc.
ER Squibb and Sons Pharmaceutical Laboratories
Ersana, Inc., Subsidiary of ER Squibb and Sons
Everylife
Fallek Products Co., Inc.
Farmila Farmaceutica
Faton Pharmaceuticals, Inc.
Fermion Oy
Ferndale Laboratories, Inc.
Fisons Corp.
Forest Laboratories, Inc.
Forest Pharmaceuticals, Inc.
Forrest Laboratories, Inc.
G & W Co.
Glenwood Laboratories, Inc.
Global Pharmaceutical Corp.
Gruppo Lepetit SpA Subsidiary of Merrell Dow Pharmaceuticals, Inc.
Heather Drug Co., Inc.
Herald Pharmacal, Inc.
Hoffmann La Roche, Inc.
ICI Ltd.
Ingram Pharmaceutical Co.
Inwood Laboratories, Inc., Subsidiary of Forest Laboratories, Inc.

ISF
Kasar Laboratories Division of Kasar Co.
Kasco EFCO Laboratories, Inc., Division of Byk Gulden, Inc.
KV Pharmaceutical, Co.
Lannett Co, Inc.
Lederle Laboratories Division of American Cyanamid Co.
Leiner Health Products, Inc.
Lemmon Co. Subsidiary of Tag Pharmaceutical, Inc.
Life Laboratories, Inc.
Linden Laboratories, Inc., Subsidiary of Chromalloy American Corp.
Luitpold Pharmaceuticals, Inc.
Marshall Pharmacal Corp.
MD Pharmaceutical, Inc.
Medev, Inc.
Mission Pharmacal Co.
M M Mast & Co.
Mutual Pharmaceutical Company, Inc.
Newtron Pharmaceuticals, Inc.
Novartis Pharmaceuticals Corp.
Nylos Trading Co., Inc.
Panray Corp Subsidiary of Ormont Drug and Chemical Co., Inc.
Parke Davis Division of Warner Lambert Co.
Pasadena Research Laboratories, Inc.
Penick Corp.
Person and Covey, Inc.
Pfizer Co.
Pfizer, Inc.
Pharmaceutical Associates, Inc.
Pharmacia and Upjohn Co.
Pharmadyne Laboratories, Inc.
Pharmavite Pharmaceuticals
Phoenix Laboratories, Inc.
Polfa Pharmaceutical Works
Premo Pharmaceutical Laboratories, Inc.
Purepac Pharmaceutical Co.
Rachelle Laboratories Italia SpA
Reed and Carnrick Division of Block Drug Co., Inc.
Rexar Pharmacal
Richlyn Laboratories, Inc.
Robinson Laboratories, Inc.
Roussel Corp.
Rovers Pharmacal, Inc.
RP Scherer Corp.
Sandoz, Inc.
Scherer Laboratories, Inc.
Schering Corp. Subsidiary of Schering Plough Corp.
Smith Kline and French Laboratory Co. Subsidiary of SmithKline Beckman
Societa Italiana Prodotti Schering
Sperti Drug Products, Inc.
Stayner Corp.
Steri Med, Inc. Subsidiary of Ketchum Laboratories, Inc.
Tablicaps, Inc.
Tera Pharmaceuticals, Inc.
Teva Pharmaceuticals USA, Inc.
Titan Pharmacal, Co.
Travenol Laboratories, Inc.
Valeant Pharmaceuticals International
Watson Laboratories, Inc.
Western Research Laboratories, Inc.
West-Ward Pharmaceutical Corp.
Wharton Laboratories, Inc., Division of US Ethicals
Whiteworth Towne Paulsen, Inc.
Wyeth Ayerst Laboratories
Zenith Laboratories, Inc.

TABLE 1—ABBREVIATED NEW DRUG APPLICATION (ANDA) NUMBERS WITH PRODUCT NAMES

ANDA No.	Product name
60881	Tetracycline hydrochloride.
60913	Dicloxacillin sodium.
60919	Neomycin sulfate; bacitracin.
60965	Neomycin sulfate; polymyxin b sulfates; bacitracin.
61046	Penicillin g sodium.
61091	Phenethicillin potassium.
61093	Penicillin g potassium.
61097	Troleandomycin.
61099	Doxycycline hyclate.
61102	Oxytetracycline calcium.
61114	Chlortetracycline hydrochloride.
61116	Ampicillin trihydrate.
61117	Phenethicillin potassium.
61118	Cloxacillin sodium.
61119	Dicloxacillin sodium.
61120	Tetracycline.
61121	Tetracycline phosphate.
61142	Penicillin g potassium.
61144	Amphotericin b.
61145	Penicillin g potassium.
61152	Tetracycline hydrochloride.
61170	Bacitracin.
61171	Bacitracin zinc.
61191	Tetracycline hydrochloride.
61192	Tetracycline hydrochloride.
61194	Paromomycin sulfate.
61197	Tetracycline hydrochloride.
61382	Ampicillin trihydrate.
61420	Tetracycline.
61422	Oxytetracycline hydrochloride.
61423	Oxytetracycline.
61428	Chloramphenicol palmitate.
61429	Tetracycline.
61430	Chloramphenicol.
61431	Chloramphenicol.
61432	Chloramphenicol sodium succinate.
61433	Chloramphenicol sodium succinate.
61440	Tetracycline hydrochloride.
61442	Erythromycin estolate.
61556	Tetracycline.
61564	Methacycline hydrochloride.
61565	Paromomycin sulfate.
61570	Hetacillin.

TABLE 1—ABBREVIATED NEW DRUG APPLICATION (ANDA) NUMBERS WITH PRODUCT NAMES—Continued

ANDA No.	Product name
61581	Tetracycline hydrochloride.
61582	Tetracycline.
61597	Ampicillin trihydrate.
61604	Ampicillin sodium.
61608	Tetracycline hydrochloride.
61629	Penicillin g benzathine.
61630	Streptomycin sulfate.
61631	Dihydrostreptomycin sulfate.
61749	Dicloxacillin sodium.
61750	Ampicillin trihydrate.
61751	Doxycycline hyclate.
61754	Griseofulvin.
61775	Tetracycline.
61777	Mitomycin.
61778	Erythromycin.
61779	Erythromycin stearate.
61784	Tetracycline hydrochloride.
61795	Oxacillin sodium.
61796	Oxacillin sodium.
61797	Methicillin sodium.
61804	Carbenicillin indanyl sodium.
61824	Tetracycline.
61825	Tetracycline.
61843	Penicillin v potassium.
61844	Ampicillin.
61845	Ampicillin trihydrate.
61852	Tetracycline phosphate complex.
61993	Cloxacillin sodium.
62016	Amoxicillin trihydrate.
62019	Tetracycline hydrochloride.
62020	Tetracycline phosphate.
62344	Cloxacillin sodium.
80004	Propylthiouracil.
80088	Sulfadiazine.
80200	Succinylcholine chloride.
80313	Methyltestosterone.
80350	Prednisone.
80351	Prednisolone.
80359	Prednisone.
80452	Hydrocortisone.
80456	Hydrocortisone.
80501	Diphenhydramine hydrochloride.
80559	Cyanocobalamin.
80560	Pyridoxine hydrochloride.
80561	Thiamine hydrochloride.
80616	Cyanocobalamin.
80676	Testosterone propionate.
80840	Propylthiouracil.
80943	Vitamin a palmitate.
80947	Aminosalicylate sodium.
80956	Vitamin d.
80985	Vitamin a.
83002	Diethylstilbestrol.
83003	Diethylstilbestrol.
83004	Diethylstilbestrol.
83005	Diethylstilbestrol.
83006	Diethylstilbestrol.
83007	Diethylstilbestrol.
83114	Vitamin a palmitate.
83133	Folic acid.
83134	Vitamin a.
83197	Propoxyphene hydrochloride.
83203	Niacin.
83208	Cortisone acetate.
83233	Hydrocortisone acetate.
83243	Chlorpheniramine maleate.
83258	Butabarbital sodium.
83259	Pentobarbital sodium.
83268	Butabarbital sodium.
83269	Butabarbital sodium.
83293	Propoxyphene hydrochloride.
83311	Vitamin a palmitate.

TABLE 1—ABBREVIATED NEW DRUG APPLICATION (ANDA) NUMBERS WITH PRODUCT NAMES—Continued

ANDA No.	Product name
83321	Vitamin a palmitate.
83335	Prednisolone acetate.
83343	Meprobamate.
83374	Estrogens, esterified.
83394	Chlorpheniramine maleate.
83421	Probenecid.
83439	Quinidine sulfate.
83444	Rauwolfia serpentina.
83454	Lidocaine.
83494	Meprobamate.
83503	Negatol.
83537	Secobarbital sodium.
83553	Procainamide hydrochloride.
83562	Prednisolone acetate.
83578	Butabarbital sodium.
83674	Diphenhydramine hydrochloride.
83675	Prednisolone.
83676	Prednisone.
83756	Piperazine citrate.
83772	Pyridoxine hydrochloride.
83864	Secobarbital sodium.
83865	Promethazine hydrochloride.
83867	Rauwolfia serpentina.
83880	Propoxyphene hydrochloride.
83912	Vitamin a palmitate.
83926	Ergotamine tartrate; caffeine.
83929	Cortisone acetate.
83940	Diethylstilbestrol.
83958	Propylthiouracil.
83960	Prednisolone.
83974	Trihexyphenidyl hydrochloride.
84008	Chlorpheniramine maleate.
84009	Prednisone.
84016	Dextroamphetamine hydrochloride.
84027	Promethazine hydrochloride.
84073	Benzthiazide.
84080	Promethazine hydrochloride.
84097	Dicyclomine hydrochloride.
84237	Niacin.
84257	Dicyclomine hydrochloride.
84262	Phenylbutazone.
84263	Dimenhydrinate.
84293	Dicyclomine hydrochloride.
84298	Hydrochlorothiazide.
84311	Phenylbutazone.
84365	Dexamethasone sodium phosphate.
84382	Meclizine hydrochloride.
84410	Trichlormethiazide.
84428	Propantheline bromide.
84459	Propylthiouracil.
84485	Phentermine hydrochloride.
84552	Aminophylline.
84559	Theophylline.
84632	Aminophylline.
84670	Chlordiazepoxide.
84671	Chlordiazepoxide.
84672	Chlordiazepoxide.
84695	Phentermine hydrochloride.
84736	Rescinnamine.
84846	Methocarbamol.
84856	Cortisone acetate.
84871	Prednisolone acetate.
84906	Reserpine; hydrochlorothiazide.
84979	Hydrocortisone.
85033	Methocarbamol.
85115	Prednisone.
85170	Prednisolone.
85174	Cortisone acetate.
85185	Diethylpropion hydrochloride.
85207	Reserpine.
85242	Chlordiazepoxide hydrochloride.
85258	Chlordiazepoxide.

TABLE 1—ABBREVIATED NEW DRUG APPLICATION (ANDA) NUMBERS WITH PRODUCT NAMES—Continued

ANDA No.	Product name
85259	Chlordiazepoxide.
85270	Methyltestosterone.
85280	Chlordiazepoxide hydrochloride.
85281	Chlordiazepoxide hydrochloride.
85308	Phenytoin sodium.
85325	Methylprednisolone.
85360	Chlordiazepoxide hydrochloride.
85405	Perphenazine.
85412	Tripelennamine hydrochloride.
85419	Quinidine sulfate.
85439	Butalbital; aspirin; phenacetin; caffeine.
85442	Chlordiazepoxide hydrochloride.
85489	Probenecid.
85516	Theophylline.
85576	Estradiol.
85590	Oxyphenbutazone.
85592	Brompheniramine maleate.
85613	Phendimetrazine tartrate.
85647	Amitriptyline hydrochloride.
85649	Amitriptyline hydrochloride.
85678	Amitriptyline hydrochloride.
85680	Amitriptyline hydrochloride.
85696	Isoniazid; pyridoxine hydrochloride.
85707	Isopropamide iodide.
85716	Hydralazine hydrochloride.
85717	Hydralazine hydrochloride.
85725	Phendimetrazine tartrate.
85730	Cyanocobalamin.
85731	Phentermine hydrochloride.
85760	Chlorothiazide.
85774	Methyltestosterone.
85776	Methyltestosterone.
85806	Reserpine; hydralazine hydrochloride; hydrochlorotiazide.
85807	Meclizine hydrochloride.
85808	Meclizine hydrochloride.
85812	Propoxyphene hydrochloride.
85901	Imipramine hydrochloride.
85918	Ergotamine tartrate; caffeine.
85942	Amitriptyline hydrochloride.
85943	Triamcinolone acetonide.
85946	Amitriptyline hydrochloride.
85947	Amitriptyline hydrochloride.
85948	Amitriptyline hydrochloride.
85949	Amitriptyline hydrochloride.
85950	Amitriptyline hydrochloride.
85954	Methyltestosterone.
85955	Methyltestosterone.
85972	Acetaminophen; salicylamide; caffeine; codeine phosphate.
86068	Triamcinolone acetonide.
86111	Amodiaquine hydrochloride.
86115	Bethanechol chloride.
86125	Quinidine sulfate.
86128	Chlorpromazine.
86131	Acetazolamide.
86207	Hydrocortisone acetate.
86211	Phendimetrazine tartrate.
86253	Trihexyphenidyl hydrochloride.
86254	Chlorothiazide.
86279	Hydrochlorothiazide.
86286	Butalbital; aspirin; phenacetin; caffeine.
86288	Amitriptyline hydrochloride.
86316	Orphenadrine citrate.
86317	Diphenoxylate hydrochloride; atropine sulfate.
86318	Hydrochlorothiazide.
86319	Hydrochlorothiazide.
86320	Methocarbamol.
86321	Methocarbamol.
86322	Prednisone.
86324	Prednisone.
86326	Butalbital; aspirin; phenacetin; caffeine.
86327	Trifluoperazine hydrochloride.
86334	Hydrocortisone.

TABLE 1—ABBREVIATED NEW DRUG APPLICATION (ANDA) NUMBERS WITH PRODUCT NAMES—Continued

ANDA No.	Product name
86343	Thioridazine hydrochloride.
86345	Thioridazine hydrochloride.
86354	Thioridazine hydrochloride.
86377	Hydrochlorothiazide.
86400	Hydrocortisone acetate.
86401	Hydrocortisone acetate.
86404	Phendimetrazine tartrate.
86407	Phendimetrazine tartrate.
86411	Dimenhydrinate.
86412	Dicyclomine hydrochloride.
86430	Phendimetrazine;adipic acid.
86431	Phendimetrazine.
86436	Homatropine methylbromide.
86437	Homatropine hydrobromide.
86438	Trifluoperazine hydrochloride.
86443	Trifluoperazine hydrochloride.
86447	Trifluoperazine hydrochloride.
86476	Diazepam.
86510	Phentermine hydrochloride.
86515	Phentermine hydrochloride.
86529	Dicyclomine hydrochloride; phenobarbital.
86555	Phendimetrazine tartrate.
86563	Dicyclomine hydrochloride; phenobarbital.
86564	Phenobarbital; atropine sulfate; hyoscyamine sulfate; hyscyamine hydrobromide.
86565	Phenobarbital; hyoscyamine sulfate; atropine sulfate; scopolamine hydrobromide.
86566	Dicyclomine hydrochloride; phenobarbital.
86581	Chlordiazepoxide hydrochloride; clidinium bromide.
86591	Phenobarbital; hyoscyamine sulfate; atropine sulfate; scopolamine hydrobromide.
86625	Dicyclomine hydrochloride.
86627	Meprobamate; tridihexethyl chloride.
86629	Meprobamate; tridihexethyl chloride.
86630	Piperidolate hydrochloride; phenobarbital.
86634	Chlordiazepoxide hydrochloride; clidinium bromide.
86644	Piperidolate hydrochloride.
86647	Chlordiazepoxide hydrochloride; clidinium bromide.
86650	Anisotropine methylbromide; phenobarbital.
86654	Meprobamate; tridihexethyl chloride.
86655	Atropine sulfate; hyoscyamine sulfate; phenobarbital; scopolamine hydrobromide.
86657	Phenobarbital; atropine sulfate; hyoscyamine sulfate; scopolamine hydrobromide.
86658	Meprobamate; tridihexethyl chloride.
86665	Phenobarbital; atropine sulfate; hyoscyamine sulfate; scopolamine hydrobromide.
86667	Chlordiazepoxide hydrochloride; clidinium bromide.
86668	Phenobarbital; belladonna alkaloid malates, l-.
86669	Dicyclomine hydrochloride.
86670	Atropine sulfate; hyoscyamine sulfate; phenobarbital; scopolamine hydrobromide.
86671	Phenobarbital; hyoscyamine sulfate.
86674	Meprobamate; tridihexethyl chloride.
86675	Butabarbital sodium; simethicone; atropine sulfate; hyoscyamine sulfate; scopoamine.
86685	Chlordiazepoxide hydrochloride; clidinium bromide.
86687	Phenobarbital; belladonna extract.
86692	Amobarbital; belladonna.
86694	Oxyphencyclimine hydrochloride; phenobarbital.
86696	Phenobarbital; hyoscyamine sulfate; atropine sulfate; scopolamine hydrobromide.
86701	Atropine sulfate; phenobarbital.
86703	Phenobarbital; hyoscyamine sulfate; atropine sulfate; scopolamine hydrobromide.
86704	Phenobarbital; hyoscyamine sulfate; atropine sulfate; scopolamine hydrobromide.
86706	Meprobamate; tridihexethyl chloride.
86708	Cyproheptadine hydrochloride.
86709	Meprobamate; tridihexethyl chloride.
86721	Procainamide hydrochloride.
86770	Nitroglycerin.
86773	Triamcinolone diacetate.
86774	Erythrityl tetranitrate.
86775	Isosorbide dinitrate.
86776	Pentaerythritol tetranitrate.
86777	Nitroglycerin.
86779	Nitroglycerin.
86782	Nitroglycerin.
86783	Isosorbide dinitrate.
86784	Pentaerythritol tetranitrate.
86785	Pentaerythritol tetranitrate.
86786	Isosorbide dinitrate.

TABLE 1—ABBREVIATED NEW DRUG APPLICATION (ANDA) NUMBERS WITH PRODUCT NAMES—Continued

ANDA No.	Product name
86789	Estradiol valerate.
86794	Dipyridamole.
86799	Atropine sulfate; phenobarbital.
86838	Pentaerythritol tetranitrate.
86839	Isosorbide dinitrate.
86868	Chlorpromazine hydrochloride.
86882	Hydrocortisone.
86897	Phenobarbital; hyoscyamine hydrobromide; atropine sulfate; scopolamine hydrobromide.
86921	Chlordiazepoxide hydrochloride; clidinum bromide.
86970	Aminophylline.
86976	Doxylamine succinate; pyridoxine hydrochloride.
86991	Probenecid.
86999	Butalbital; aspirin; phenacetin; caffeine.
87000	Hydralazine hydrochloride.
87041	Phendimetrazine tartrate.
87064	Piperazine citrate.
87069	Sulfisoxazole acetyl.
87096	Phentermine hydrochloride.
87097	Phentermine hydrochloride.
87098	Phentermine hydrochloride.
87099	Phentermine hydrochloride.
87106	Ergotamine tartrate; caffeine.
87112	Spironolactone.
87116	Reserpine; chlorothiazide.
87123	Benzthiazide.
87124	Benzthiazide.
87125	Diphenhydramine hydrochloride.
87134	Promethazine hydrochloride.
87166	Phentolamine hydrochloride.
87172	Theophylline.
87198	Belladonna alkaloid malates, l-; phenobarbital.
87379	Quinidine gluconate.
87443	Homatropine methylbromide; phenobarbital.

Dated: June 8, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Secretary's Advisory Committee on Heritable Disorders in Newborns and Children

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice of Request for Nominations of Non-Voting Secretary's Advisory Committee on Heritable Disorders in Newborns and Children (SACHDNC) members to serve as representatives of organizations or interest groups.

SUMMARY: HRSA is requesting applications to fill three (3) vacancies for non-voting organizational representatives on the SACHDNC.

Authority: Section 1111 of the Public Health Service (PHS) Act, 42 U.S.C. 300b–10, as amended. The SACHDNC also is governed by the provisions of Public Law 92–463, as amended (5 U.S.C. App. 2), and 41 CFR part 102–3, which sets forth standards for the formation and use of advisory committees.

DATES: The agency must receive written applications from nominees (including a letter of support from an appropriate official of the organization with which affiliated) or the nominee's organization, on or before August 1, 2012.

ADDRESSES: Submit written applications to Sara Copeland, M.D., Designated Federal Official (DFO), SACHDNC; and, Chief, Genetic Services Branch, Maternal and Child Health Bureau, Health Resources and Services Administration, Room 18A–19, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857. Applications may also be sent to *Screening@hrsa.hhs.gov*.

FOR FURTHER INFORMATION CONTACT: Debi Sarkar, M.P.H., Genetic Services Branch, Maternal and Child Health Bureau, HRSA, at *dsarkar@hrsa.gov* or (301) 443–1080. A copy of the SACHDNC Charter and list of the current membership may be obtained by contacting Ms. Sarkar or by accessing the SACHDNC Web site at *http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/*.

SUPPLEMENTARY INFORMATION: The SACHDNC is directed to review and report regularly on newborn and childhood screening practices for heritable disorders and recommend improvements in the national newborn and childhood heritable screening programs.

The SACHDNC provides the Secretary with recommendations, advice, and technical information regarding the application of technologies, policies, guidelines, and standards for: (a) Effectively reducing morbidity and mortality in newborns and children having, or at risk for, heritable disorders; and (b) enhancing the ability of the State and local health agencies to provide for newborn and child screening, counseling, and health care services for newborns and children having, or at risk for, heritable disorders.

Specifically, HRSA is requesting applications for three (3) non-voting organizational representatives to serve on the SACHDNC: Two (2) at large representatives of a public health constituency, medical professional