



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SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing its intention to deem to be withdrawn any abbreviated new drug applications (ANDAs) that have been determined to be incomplete and as to which the ANDA applicant has not communicated with FDA since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 Each of these applications will be deemed to have been withdrawn voluntarily by the applicant unless the applicant informs the Agency in writing that it intends to actively pursue approval of the application(s) (see DATES).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 [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. .

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 FDA’s regulations provide that the Agency will consider withdrawn any application for which the applicant has not contacted the Agency about its intention regarding such application within 1 year after issuance of a complete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 [INSERT DATE 60 DAYS

AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER], 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.
 Alparma 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.
 Dermalave 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 Number	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

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
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	Rescinamine
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
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; hydrochlorothiazide
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 acetate
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
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; hyoscyamine 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; scopolamine
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
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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