potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,251 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by April 24, 2007. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by August 22, 2007. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 3, 2007.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. E7–3128 Filed 2–22–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004P–0262]

Withdrawal of Approval of 128 Suitability Petitions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 128 suitability petitions. This action is being taken in accordance with the Pediatric Research Equity Act of 2003 (PREA). Prior to PREA's enactment, FDA had approved these suitability petitions to permit abbreviated new drug applications (ANDAs) to be submitted for drugs that had a different active ingredient, dosage form, or route of administration than their reference listed drugs (RLDs). However, these approval decisions are being withdrawn because ANDAs were never submitted and PREA requires that all applications submitted on or after April 1, 1999, for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration contain an assessment of the safety and effectiveness of the drug for the claimed indications in relevant pediatric subpopulations unless the requirement is waived or deferred. This action is being taken without prejudice. Any of the suitability petitions may be resubmitted for action by the agency in accordance with current law.

DATES: This notice is effective March 26, 2007.

FOR FURTHER INFORMATION CONTACT: Cecelia M. Parise, Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5845.

SUPPLEMENTARY INFORMATION: PREA (Public Law 108–155) was enacted on December 3, 2003. Among other things, section 2 of PREA requires that all drug applications submitted on or after April 1, 1999, for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration contain an assessment of the safety and effectiveness of the drug for the claimed indications in relevant pediatric subpopulations unless the requirement is waived or deferred. As a result, FDA is withdrawing its approval for 128 suitability petitions for which ANDAS were never submitted. The approval decisions, made prior to the enactment of PREA, would have permitted ANDAs to be submitted for certain drugs that have a different active ingredient, dosage form, or route of administration than their RLDs. No ANDAs were submitted for these drugs pursuant to these suitability petitions prior to April 1, 1999, and any such application submitted on or after April 1, 1999, would be required to contain the safety and effectiveness assessments required by PREA, unless waived or deferred. According to § 314.93(e)(1)(i) (21 CFR 314.93(e)(1)(i)), a suitability petition may not be approved if investigations must be conducted to show the safety and effectiveness of the drug product. In addition, according to § 314.93(f), FDA may withdraw approval of a suitability petition if it receives information demonstrating that the petition no longer satisfies the conditions of § 314.93(e). Under PREA, safety and effectiveness investigations in pediatric subpopulations would be required for the drug products proposed by these suitability petitions, unless the requirement is waived or deferred. Therefore, these suitability petitions no longer satisfy the regulatory requirements for approval. Pursuant to § 314.93(f), FDA is withdrawing approval of the 128 suitability petitions listed in the following table:

Petition No.	Drug	Petitioner
82N–0032/CP6	Chlorzoxazone 500 milligrams (mg)	Mikart, Inc.
84N–0116/CP1	Disopyramide Phosphate 200 mg or 300 mg	Biocraft Laboratories, Inc.
84P–0228/CP1	Acetaminophen 500 mg, Codeine Phosphate 30 mg or 60 mg	McNeil Pharmaceutical
85P–0067/CP1	Methyltestosterone 25 mg	Star Pharmaceuticals
85P–0074/CP1	Hydralazine Hydrochloride 25 mg/5 milliliters (mL)	Roxane Laboratories, Inc.
85P–0081/CP1	Flurazepam Hydrochloride 30 mg/mL	Do.
85P–0084/CP1	Vincristine Sulfate 2 mg	Bristol Laboratories

Petition No.	Drug	Petitioner
85P–0091/CP1	Flurazepam Hydrochloride 15 mg/5 mL	Roxane Laboratories, Inc.
85P–0095/CP1	Brompheniramine Maleate 12 mg, Pseudoephedrine Hydrochloride 120 mg	UAD Laboratories, Inc.
85P–0129/CP1	Propranolol Hydrochloride 160 mg	Verex Laboratories, Inc.
85P–0140/CP1	Dexbrompheniramine Maleate 6 mg, Pseudoephedrine Hydrochloride 120 mg	Central Pharmaceuticals, Inc.
85P–0140/CP2	Dexbrompheniramine Maleate 6 mg, Pseudoephedrine Sulfate 120 mg	Do.
85P–0147/CP1	Ketoconazole 20 mg/mL	Janssen Pharmaceutica
85P–0197/CP1	Propranolol Hydrochloride 80 mg, 120 mg, 160 mg	Forest Laboratories
85P–0215/CP1	Disulfiram 500 mg/30 mL	Paddock Laboratories
85P–0238/CP2	Dexbrompheniramine Maleate 6 mg, Phenylpropanolamine Hydrochloride 75 mg	Bock Pharmacal Co.
85P–0269/CP1	Codeine Phosphate 10 mg/5 mL, Dexbrompheniramine Maleate 1 mg/5 mL, Phenylpropanolamine Hydrochloride 12.5 mg/5 mL	Do.
85P–0423/CP1	Benztropine Mesylate 0.5 mg/5 mL	RIM Consulting Corp.
85P–0492/CP1	Azatadine Maleate 1 mg, Phenylpropanolamine Hydrochloride 75 mg	Smith, Kline & French Laboratories
85P–0499/CP1	Diazepam 2 mg/5 mL	Carolina Medical Products Co.
85P–0510/CP1	Spironolactone 25 mg/5 mL	Do.
85P–0515/CP1	Lorazepam 0.5 mg, 1 mg, or 2 mg	Wyeth Laboratories, Inc.
85P–0516/CP1	Oxazepam 15 mg or 30 mg	Do.
85P–0543/CP1	Acetaminophen 300 mg, Codeine Phosphate 30 mg	Softan, Inc.
85P–0543/CP2	Acetaminophen 500 mg, Codeine Phosphate 7.5 or 15 mg	Do.
85P–0543/CP3	Acetaminophen 500 mg, Oxycodone Hydrochloride 5 mg	Do.
85P–0563/CP1	Ibuprofen 300, 400, or 600 mg	Do.
85P–0581/CP1	Acetaminophen 500 mg, Propoxyphene Hydrochloride 32 mg	Do.
86P–0045/CP1	Propranolol Hydrochloride 10, 20, 40, 60, 80, 90 mg	Nutripharm, Inc.
86P–0055/CP1	Spironolactone 25 mg/5 mL	Carolina Medical Products Co.
86P–0123/CP1	Cholestyramine 4 grams (g)	Parke-Davis, Division of Warner-Lambert Co.
86P–0200/CP1	Acetaminophen 650 mg, Codeine Phosphate 15 mg	Mikart, Inc.
86P–0242/CP1	Floxuridine 500 mg/5 mL	Quad Pharmaceuticals, Inc.
86P–0292/CP1	Lorazepam 1 mg/5 mL	Roxane Laboratories, Inc.
86P–0359/CP1	Aspirin 356.4 mg, Caffeine 30 mg, Dihydrocodeine Bitartrate 16 mg	Central Pharmaceuticals, Inc.
86P–0361/CP1	Acetaminophen 325 mg, Aspirin 325 mg, Codeine Phosphate 30 mg	Bock Pharmacal Co.

Petition No.	Drug	Petitioner
86P–0427/CP1	Hydrochlorothiazide 50 mg, Triamterene 75 mg	Par Pharmaceutical, Inc.
86P–0474/CP1	Cholestyramine 500 mg	Bristol-Myers Squibb
87P–0004/CP1	Fluocinonide 0.05%	Richard Hamer Assoc.
87P–0037/CP1	Lorazepam 0.5 mg, 1 mg, 2 mg	Applied Laboratories, Inc.
87P–0101/CP1	Verapamil Hydrochloride 40 mg/5 mL or 80 mg/5 mL	MY-K Laboratories, Inc.
87P–0233/CP1	Verapamil Hydrochloride 120 mg or 240 mg	Searle Research & Development
87P–0242/CP1	Ibuprofen 800 mg	Sidmak Laboratories, Inc.
87P–0265/CP1	Dexbrompheniramine Maleate 6 mg, Phenypropanolamine Hydrochloride 75 mg	Bock Pharmacal Co. (King & Spalding)
87P–0268/CP1	Loperamide Hydrochloride 2 mg	Kross, Inc.
87P–0301/CP1	Cholestyramine Resin 4 g	Ciba-Geigy Corp.
87P–0314/CP1	Clemastine Fumarate 1.34 mg, Pseudoephedrine Hydrochloride 120 mg	Sandoz Consumer Healthcare Group
87P–0323/CP1	Acetaminophen 160 mg/5 mL, Codeine Phosphate 6 mg/5 mL	Kleinfeld, Kaplan & Becker
87P–0335/CP1	Triamterene 50 mg, Hydrochlorothiazide 25 mg	Par Pharmaceutical, Inc.
87P–0340/CP1	Nifedipine 10 mg or 20 mg	Do.
87P–0367/CP1	Phenytoin Sodium 100 mg, 250 mg/vial	Lyphomed, Inc.
87P–0399/CP1	Propranolol Hydrochloride 40 mg or 80 mg/5 mL, Hydrochlorothiazide 25 mg/5 mL	Burditt, Bowles, Radzius & Rudberry
88P–0011/CP1	Cyclophosphamide 20 mg/mL, 500 mL pharmacy bulk pack (PBP)	Baxter Healthcare Corp.
88P–0036/CP1	Chlorhexidine Gluconate 0.5%	Arent, Fox, Kinter, Plotkin & Kahn
88P–0061/CP1	Homatropine Methylbromide 1.5 mg, Hydrocodone Bitartrate 5 mg	Kleinfeld, Kaplan & Becker
88P–0149/CP1	Leucovorin Calcium 1 mg/mL	Roxane Laboratories, Inc.
88P–0277/CP1	Quinidine Sulfate 300 mg	A. H. Robins
88P–0350/CP1	Clemastine Fumarate 1.34 mg, Phenylpropanolamine Hydrochloride 75 mg	Scientific Consulting of VA, Inc.
88P–0379/CP1	Cyclophosphamide 20 mg/mL, 250 mL PBP	Baxter Healthcare Corp.
88P–0391/CP1	Prednisone 1 mg, 2.5 mg, 5 mg, 10 mg, 20 mg, 25 mg, or 50 mg	B.F. Ascher & Co., Inc.
89P–0028/CP1	Hydrocortisone Valerate 0.2%	McKenna, Conner & Cuneo
89P–0029/CP1	Hydrocortisone Valerate 0.2%	Do.
89P–0071/CP1	Morphine Sulfate 30 mg	Ethypharm/Oxford Research Intl. Corp.
89P–0399/CP1	Carbamazepine 200 mg/5 mL	Guidelines, Inc.
89P–0435/CP1	Pentamidine Isethionate 100 mg/mL	Astra Pharmaceutical Products, Inc.
90P–0049/CP1	Hydrocortisone Acetate 2.5% or 1%	Ferndale Laboratories, Inc.
90P–0084/CP1	Chlorzoxazone 250 mg	Mikart, Inc.
90P–0154/CP1	Hydrocortisone Acetate 1%	Ferndale Laboratories, Inc.
90P–0198/CP1	Clobetasol Propionate 0.05%, RLD = Temovate	Kross, Inc.

Petition No.	Drug	Petitioner
90P–0436/CP1	Nifedipine 30 mg, 60 mg, 90 mg	KV Pharmaceutical Co.
91P–0348/CP1	Albuterol Sulfate 4 mg	Richard Hamer Associates, Inc.
92P–0048/CP2	Triazolam 0.125 mg/5 mL	Roxane Laboratories, Inc.
92P–0101/CP1	Hydrocortisone Acetate 2.5%	Hogan & Hartson
92P–0282/CP1	Acetaminophen 150 mg, Aspirin 180 mg, Hydrocodone Bitartrate 5 mg	Mikart, Inc.
92P–0282/CP2	Acetaminophen 150 mg, Aspirin 180 mg, Hydrocodone Bitartrate 7.5 mg	Do.
92P–0282/CP3	Acetaminophen 150 mg, Aspirin 180 mg, Hydrocodone Bitartrate 2.5 mg	Do.
92P–0282/CP4	Acetaminophen 150 mg, Aspirin 180 mg, Hydrocodone Bitartrate 10 mg	Do.
92P–0332/CP1	Propranolol Hydrochloride 40 mg	Flemington Pharmaceutical Corp.
92P–0335/CP1	Albuterol Sulfate 2 mg, 4 mg	WE Pharmaceuticals, Inc.
92P–0336/CP1	Prednisone 5 mg or 10 mg	Do.
92P–0381/CP1	Cytarabine 20 mg/mL, 12.5 mL	Bristol-Myers Squibb Co.
92P–0500/CP1	Timethoprim 25 mg/5 mL	Ascent Pharmaceuticals, Inc.
93P–0048/CP1	Cimetidine 200, 300, 400 or 800 mg	Flemington Pharmaceuticals Corp.
93P–0049/CP1	Propranolol Hydrochloride 10, 20, 60, 80, 90 mg	Do.
93P–0314/CP1	Acetaminophen 500 mg, Codeine Phosphate 45 mg	Mikart, Inc.
93P–0332/CP1	Loperamide Hydrochloride 1 mg	Asta Medica GmbH
93P–0333/CP1	Prednisone 1, 2.5, 20, 50 mg	Dura Pharmaceuticals
93P–0346/CP1	Acetaminophen 325 mg, Butalbital 50 mg, Caffeine 40 mg, Hydrocodone Bitartrate 5 mg	Mikart, Inc.
93P–0367/CP1	Terfenadine 60 mg, Pseudoephedrine 120 mg	Eurand America
93P–0446/CP1	Morphine Sulfate 15 mg, 60 mg, 90 mg, 100 mg	Ethypharm
93P–0459/CP1	Methyltestosterone 25 mg	ICN Pharmaceuticals, Inc.
94P–0182/CP1	Acetaminophen 120 mg, Codeine Phosphate 12 mg	WE Pharmaceuticals, Inc.
94P–0186/CP1	Sulfamethoxazole 200 mg, Trimethoprim 40 mg	Dura Pharmaceuticals
94P–0199/CP1	Lorazepam 1 mg/10 mL	Roxane Laboratories, Inc.
94P–0210/CP1	Acetaminophen 150 mg, Aspirin 180 mg, Codeine Phosphate 60 mg	Mikart, Inc.
94P–0211/CP1	Acetaminophen 150 mg, Aspirin 180 mg, Codeine Phosphate 30 mg	Do.

Petition No.	Drug	Petitioner
94P–0212/CP1	Acetaminophen 150 mg, Aspirin 180 mg, Codeine Phosphate 15 mg	Do.
94P–0263/CP1	Fluorouracil 5%	Bradley Pharmaceuticals, Inc.
94P–0432/CP1	Methylprednisolone 16 mg, 24 mg, 32 mg	Dura Pharmaceuticals
94P–0433/CP1	Leucovorin Calcium 10 mg/mL 350 mg vial	Lederle Laboratories
94P–0433/CP2	Leucovorin Calcium 10 mg/mL 5 mL vial	Do.
95P–0008/CP1	Captopril 25 mg/mL	Roxane Laboratories, Inc.
95P–0100/CP1	Carbidopa/Levodopa 25/100 mg, 25/250 mg	Athena Neurosciences, Inc.
95P–0223/CP1	Hydrocortisone Butyrate 0.1%	McKenna & Cuneo, L.L.P.
95P–0268/CP1	Acyclovir Sodium 5 mg/mL	Wilmer, Cutler, Pickering
95P–0277/CP1	Cholestyramine 2 g	Mayrand Pharmaceuticals, Inc.
95P–0279/CP1	Butalbital 50 mg, Acetaminophen 325 mg, Caffeine 40 mg, Hydrocodone Bitartrate 10 mg	Mikart, Inc.
95P–0279/CP2	Butalbital 50 mg, Acetaminophen 325 mg, Caffeine 40 mg, Hydrocodone Bitartrate 7.5 mg	Do.
95P–0279/CP3	Butalbital 50 mg, Acetaminophen 500 mg, Caffeine 40 mg, Hydrocodone Bitartrate 10 mg	Do.
95P–0279/CP4	Butalbital 50 mg, Acetaminophen 500 mg, Caffeine 40 mg, Hydrocodone Bitartrate 7.5 mg	Do.
95P–0326/CP1	Nifedipine 30 mg, 60 mg, 90 mg	KV Pharmaceutical Co.
95P–0328/CP1	Metronidazole 0.75%	RNB Pharmaceutical Co.
96P–0018/CP1	Potassium Chloride 20 milliequivalents (meq)	KV Pharmaceutical Co.
96P–0021/CP1	Aspirin 650 mg Butalbital 50 mg	Savage Laboratories, Division of Altana, Inc.
96P–0054/CP1	Potassium Chloride 10 meq	KV Pharmaceutical Co.
96P–0079/CP1	Pentoxyfylline 400 mg	Do.
96P–0307/CP1	Acyclovir 5%	Pitney, Hardin, Kipp & Szuch
96P–0376/CP1	Hydrocortisone Acetate 90 mg	Do.
96P–0510/CP1	Diltiazem Hydrochloride 120 mg, 180 mg, 240 mg, RLD = Cardiazem CD	Labopharm, Inc.
97P–0155/CP1	Mefenamic Acid 250 mg	Pitney, Hardin, Kipp & Szuch
97P–0192/CP1	Diltiazem Hydrochloride 120 mg, 180 mg, 240 mg, RLD = Dilacor XR	Labopharm, Inc.
97P–0195/CP1	Diltiazem Hydrochloride 120 mg, 180 mg, 240 mg, RLD = Tiazac	Do.
97P–0387/CP1	Albuterol Sulfate 2 mg and 4 mg	Richard Hamer Assoc., Inc.
97P–0404/CP1	Famotidine 10 mg	Thomas Blake, R.Ph.

Petition No.	Drug	Petitioner
98P–0068/CP1	Clobetasol Propionate 0.05%, RLD = Temovate E	Richard Hamer Associates, Inc.
98P–0146/CP1	Ifosfamide 50 mg/mL, 20 mL, and 60 mL	Mitchall G. Clark
98P–0199/CP1	Captopril 25 mg/5 mL	Miran Consulting, Inc.
98P–0745/CP1	Econazole Nitrate 1%	Do.

This action is being taken without prejudice. Any of these petitions may be resubmitted for action by the agency in accordance with current law.

Dated: February 13, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–3043 Filed 2–22–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Protection and Advocacy for Individuals with Mental Illness (PAIMI) Annual Program Performance Report (OMB No. 0930–0169)—Revision

The Protection and Advocacy for Individuals with Mental Illness (PAIMI) Act, [42 U.S.C. 10801 *et seq.*] authorized funds to support protection and advocacy services on behalf of individuals with severe mental illness and severe emotional impairment who are at risk for abuse (including incidents of seclusion, restraint, and serious injuries or fatalities related to such incidents, neglect, residing in a public or private care or treatment facility. The PAIMI Program is managed by the Center for Mental Health Services (CMHS) within the Substance Abuse and Mental Health Services Administration (SAMHSA).

Under the PAIMI Act, formula grant awards are made to governor-designated protection and advocacy (P&A) systems in each of the 50 states, the District of Columbia (Mayor), the American Indian Consortium [the Dine (Navajo) and Hopi Peoples in Northern Arizona and New Mexico), and five (5) territories—American Samoa, Guam, the Northern Mariana Islands, the Commonwealth of Puerto Rico, and the U.S. Virgin Islands. The awards are used to provide legal-based advocacy services which ensure protection against violation of the constitutional and federal rights of individuals with significant (severe) mental illness (adults) and significant (severe) emotional impairment.

In 2000, the PAIMI Act amendments, created a 57th P&A system—the American Indian Consortium and authorized P&A systems to serve PAIMI-eligible individuals, as defined under the Act [42 U.S.C. at 10802 (4)], who reside in the community including their own homes. However, P&A services to PAIMI-eligible clients residing in the community is permissible only when the annual PAIMI appropriation met or exceeded $30 million, and that residents in public and private residential care or treatment facilities had service priority over community residents. The Children's Health Act of 2000 (42 U.S.C. 290aa et seq.), also referenced State P&A authority to obtain information on incidents of seclusion, restraint, and related deaths in certain facilities.

The PAIMI Act requires each of the 57 P & A systems to file an annual report, no later than January 1st, of its activities and accomplishments and to provide information on such topics as, the numbers of individuals served, types of complaints addressed, and the number of intervention strategies used to resolve the presenting issues. Under the Act, the PAIMI Advisory Council (PAC) of each P&A system is also required to submit its independent assessment of the effectiveness of the services provided to, and the activities conducted by, the P&A systems on behalf of PAIMI-eligible individuals and their family members, in a separate section of the PPR.

The Developmental Disabilities Assistance and Bill of Rights Act of 1975, referred to as the DD Act [42 U.S.C. 6042 *et seq.*], created the State P&A systems. The Administration on Developmental Disabilities, within the Administration for Children and Families, has administrative oversight of the Protection and Advocacy for Developmental Disabilities (PADD) Program. Since 1986, the Department has provided formula grant funds to the same governor-designated P&A systems to protect and advocate for individuals with significant mental illness. SAMHSA is currently waiting for the ADD to issue a Notice of Proposed Rulemaking (NPR) for the DD Act of 2000 amendments. These amendments will also govern activities fulfilled by the State P&A systems under the PAIMI Act. Therefore, to ensure to the greatest extent possible that all facets of the P&A system administered by the Department are subject to the same requirements, SAMHSA will wait until the DD Act NPR is published before revising the PAIMI Rules. [The Final PAIMI Rules were issued in 1997 and were extended in 2000 and 2004. An FRN was published May 2006 to extend the current PAIMI Rules, which will expire in 2007, until 2010].

The Substance Abuse Mental Health Services Administration (SAMHSA) is revising the PAIMI Annual Program Performance Report for the following reasons: (1) To make it consistent with the requirements of the annual reporting requirements under the PAIMI Act and the PAIMI Rules (42 CFR Part 51), as 2), and the CHA of 2000 Parts H and I; (2) to conform with the Office of Management and Budget 's (OMB)