

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 However, these approval decisions are being withdrawn because ANDAs were never submitted and PREA requires that all applications submitted on or after April 1, 1999, for a new active ingredient, new indication,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,<br>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,<br>Pseudoephedrine Hydrochloride 120 mg   | UAD Laboratories, Inc.                      |
| 85P-0129/CP1 | Propranolol Hydrochloride 160 mg   | Verex Laboratories, Inc.                    |
| 85P-0140/CP1 | Dexbrompheniramine Maleate 6 mg,<br>Pseudoephedrine Hydrochloride 120 mg   | Central Pharmaceuticals, Inc.               |
| 85P-0140/CP2 | Dexbrompheniramine Maleate 6 mg,<br>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,<br>Phenylpropanolamine Hydrochloride 75 mg  | Bock Pharmacal Co.                          |
| 85P-0269/CP1 | Codeine Phosphate 10 mg/5 mL,<br>Dexbrompheniramine Maleate 1 mg/5 mL,<br>Phenylpropanolamine Hydrochloride 12.5 mg/5 mL | Do.   |
| 85P-0423/CP1 | Benztrapine Mesylate 0.5 mg/5 mL   | RIM Consulting Corp.                        |
| 85P-0492/CP1 | Azatadine Maleate 1 mg,<br>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,<br>Codeine Phosphate 30 mg   | Softan, Inc.                                |
| 85P-0543/CP2 | Acetaminophen 500 mg,<br>Codeine Phosphate 7.5 or 15 mg  | Do.   |
| 85P-0543/CP3 | Acetaminophen 500 mg,<br>Oxycodone Hydrochloride 5 mg  | Do.   |
| 85P-0563/CP1 | Ibuprofen 300, 400, or 600 mg  | Do.   |
| 85P-0581/CP1 | Acetaminophen 500 mg,<br>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,<br>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,<br>Caffeine 30 mg,<br>Dihydrocodeine Bitartrate 16 mg  | Central Pharmaceuticals, Inc.               |
| 86P-0361/CP1 | Acetaminophen 325 mg,<br>Aspirin 325 mg,<br>Codeine Phosphate 30 mg  | Bock Pharmacal Co.                          |

| Petition No. | Drug   | Petitioner                            |
|--------------|--|---------------------------------------|
| 86P-0427/CP1 | Hydrochlorothiazide 50 mg,<br>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,<br>Phenylpropanolamine 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,<br>Pseudoephedrine Hydrochloride 120 mg             | Sandoz Consumer Healthcare Group      |
| 87P-0323/CP1 | Acetaminophen 160 mg/5 mL,<br>Codeine Phosphate 6 mg/5 mL                        | Kleinfeld, Kaplan & Becker            |
| 87P-0335/CP1 | Triamterene 50 mg,<br>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,<br>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,<br>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,<br>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%,<br>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,<br>Aspirin 180 mg,<br>Hydrocodone Bitartrate 5 mg                      | Mikart, Inc.                     |
| 92P-0282/CP2 | Acetaminophen 150 mg,<br>Aspirin 180 mg,<br>Hydrocodone Bitartrate 7.5 mg                    | Do.                              |
| 92P-0282/CP3 | Acetaminophen 150 mg,<br>Aspirin 180 mg,<br>Hydrocodone Bitartrate 2.5 mg                    | Do.                              |
| 92P-0282/CP4 | Acetaminophen 150 mg,<br>Aspirin 180 mg,<br>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,<br>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,<br>Butalbital 50 mg,<br>Caffeine 40 mg,<br>Hydrocodone Bitartrate 5 mg | Mikart, Inc.                     |
| 93P-0367/CP1 | Terfenadine 60 mg,<br>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,<br>Codeine Phosphate 12 mg   | WE Pharmaceuticals, Inc.         |
| 94P-0186/CP1 | Sulfamethoxazole 200 mg,<br>Trimethoprim 40 mg   | Dura Pharmaceuticals             |
| 94P-0199/CP1 | Lorazepam 1 mg/10 mL   | Roxane Laboratories, Inc.        |
| 94P-0210/CP1 | Acetaminophen 150 mg,<br>Aspirin 180 mg,<br>Codeine Phosphate 60 mg                          | Mikart, Inc.                     |
| 94P-0211/CP1 | Acetaminophen 150 mg,<br>Aspirin 180 mg,<br>Codeine Phosphate 30 mg                          | Do.                              |

| Petition No. | Drug   | Petitioner                                    |
|--------------|--|---|
| 94P-0212/CP1 | Acetaminophen 150 mg,<br>Aspirin 180 mg,<br>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,<br>Acetaminophen 325 mg,<br>Caffeine 40 mg,<br>Hydrocodone Bitartrate 10 mg  | Mikart, Inc.                                  |
| 95P-0279/CP2 | Butalbital 50 mg,<br>Acetaminophen 325 mg,<br>Caffeine 40 mg,<br>Hydrocodone Bitartrate 7.5 mg | Do.   |
| 95P-0279/CP3 | Butalbital 50 mg,<br>Acetaminophen 500 mg,<br>Caffeine 40 mg,<br>Hydrocodone Bitartrate 10 mg  | Do.   |
| 95P-0279/CP4 | Butalbital 50 mg,<br>Acetaminophen 500 mg,<br>Caffeine 40 mg,<br>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<br>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,<br>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,<br>RLD = Dilacor XR                            | Labopharm, Inc.                               |
| 97P-0195/CP1 | Diltiazem Hydrochloride 120 mg, 180 mg, 240 mg,<br>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%,<br>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]

**BILLING CODE 4160-01-S**

## 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)