Services will hold a public meeting of its Committee on Health Data Standards and HHS Health Data Standards Implementation Teams.

Time and Date: 9:00 a.m.–5:00 p.m., July 9, 1997.

Place: Natcher Center Auditorium, Natcher Building and Conference Center, National Institutes of Health, Bethesda, Maryland.

The Natcher Center is located on the NIH campus on Center Drive off Wisconsin Avenue. The closest Metro stop is Medical Center (on the Red Line). Attendees are urged to use Metro because visitor parking at NIH is extremely limited. A map of the NIH campus is available on the World Wide Web at: http://www.nih.gov/welcome/images/nihmap.gif

Status: Open.

Purpose: The purpose of the meeting is for representatives of the U.S. Department of Health and Human Services to meet with interested and affected parties and members of the general public to describe the current status of activities relating to the adoption of health data standards pursuant to the administrative simplification provisions of Public Law 104–191, the Health Insurance Portability and Accountability Act of 1996 (HIPAA). HHS representatives will describe the HIPAA requirements for health data standards and will provide an overview of HHS efforts in implementing the law. The role of the National Committee on Vital and Health Statistics also will be described. Representatives of each of the six HHS Implementation Teams will then offer presentations on their progress to date as well as their preliminary findings relating to standards, and will respond to questions from the public.

**Tentative Agenda**

I. Welcome and Introductions
II. HIPAA Administrative Simplification Provisions: Background and Requirements
III. Role of the NCVHS
IV. Reports from the HHS Implementation Teams (Each report will be followed by questions from attendees.)
- Infrastructure and Crosscutting Issues
- Claims and Encounter Standards
- Unique Health Identifiers
- Enrollment and Eligibility Standards
- Coding and Classification Standards
- Security Standards

V. Conclusions

The order of agenda items is subject to change. For the final agenda, please visit the HHS Data Council's Home Page at: http://aspe.os.dhhs.gov/datacncl/

*Contact Person for More Information:* Additional information may be obtained from Bill Braithwaite, Office of the Assistant Secretary for Planning and Evaluation, DHHS, Room 440–D, Humphrey Building, 200 Independence Avenue S.W., Washington, D.C. 20201, telephone (202) 260–0546, or Robert Moore, Health Care Financing Administration, DHHS, 7500 Security Blvd., Baltimore, Maryland 21244, telephone (410) 786–0948.

Dated: June 19, 1997.

**James Scanlon,**

*Director, Division of Data Policy, OPS, Office of the Assistant Secretary for Planning and Evaluation.*

[FR Doc. 97–16678 Filed 6–24–97; 8:45 am]

**BILLING CODE 4151–04–M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 93G–0359]**

### Stork CFT B.V.; Withdrawal of GRAS Affirmation Petition

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a future filing, of a petition (GRASP 3G0397) proposing that the use of collagen fiber for use as an ingredient in human food be affirmed as generally recognized as safe (GRAS).

**FOR FURTHER INFORMATION CONTACT:** Mary E. LaVecchia, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3072.

**SUPPLEMENTARY INFORMATION:** In a notice published in the **Federal Register** of December 3, 1993 (58 FR 63996), FDA announced that a petition (GRASP 3G0397) had been filed by Teepak, Inc. (now Stork CFT B.V.), c/o 1001 G St. NW., suite 500 West, Washington, DC 20001. The petition proposed that collagen fiber be affirmed as GRAS for use as an ingredient in human food. Stork CFT B.V., (formerly Teepak, Inc.) has now withdrawn the petition without prejudice to a future filing (21 CFR 171.7).

Dated: June 13, 1997.

**Alan M. Rulis,**

*Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.*

[FR Doc. 97–16685 Filed 6–24–97; 8:45 am]

**BILLING CODE 4160–01–F**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 87N–0262]**

### Merck & Co., Inc., et al.; Withdrawal of Approval of 39 New Drug Applications, 13 Abbreviated Antibiotic Applications, and 46 Abbreviated New Drug Applications

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is withdrawing approval of 39 new drug applications (NDA's), 13 abbreviated antibiotic applications (AADA's), and 46 abbreviated new drug applications (ANDA's). The holders of the applications notified the agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

**EFFECTIVE DATE:** July 25, 1997.

**FOR FURTHER INFORMATION CONTACT:** Olivia A. Vieira, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

**SUPPLEMENTARY INFORMATION:** The holders of the applications listed in the table in this document have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications. The applicants have had a hearing or have, by their request, waived their opportunity for a hearing.

| Application No. | Drug | Applicant |
|---|---|---|
| NDA 1–205 | Propadrine (Phenylephrine hydrochloride) Elixir | Merck & Co., Inc., P.O. Box 4, BLA–20, West Point, PA 19486. |
| NDA 5–151 | Percorten Acetate (desoxy-corticosterone acetate, USP Pellets. | Novartis, 556 Morris Ave., Summit, NJ 07901–1395. |
| NDA 5–587 | Phisoderm Cream | Sterling Drug, Inc., 90 Park Ave., New York, NY 10016. |
| NDA 5–786 | Ceepryn Concentrate Solution | Merrell Dow Research Institute, 2110 E. Galbraith Rd., Cincinnati, OH 45215–6300. |

| Application No. | Drug | Applicant |
|---|---|---|
| NDA 7–085 | Cyanocobalamin Injection USP, 1000 micrograms per milliliter (mL). | Warner Chilcott, Inc., Rockaway 80 Corp. Center, 100 Enterprise Dr., suite 280, Rockaway, NJ 07866. |
| NDA 8–072 | Peritrate (pentaerythritol tetranitrate) Tablets, 10, 20, and 40 milligrams (mg). | Parke-Davis, 2800 Plymouth Rd., Ann Arbor, MI 48105. |
| NDA 8–279 | Nalline Injection | Merck & Co., Inc. |
| NDA 8–319 | Butazolidin Tablets and Capsules (phenylbutazone tablets and capsules). | Ciba Geigy Corp., 556 Morris Ave., Summit, NY 07901–1398. |
| NDA 9–099 | Bonine (meclizine HCl)Chewable Tablets | Pfizer, Inc., 235 East 42d St., New York, NY 10017–5755. |
| NDA 9–637 | Hydrocortisone AC Injection(hydrocortisone acetate injection). | Akorn, Inc., P.O. Box 1220, Decatur, IL 62525. |
| NDA 10–585 | LERITINE Tablets | Merck & Co., Inc. |
| NDA 11–109 | Peritrate SA Tablets, 80 mg | Parke-Davis. |
| NDA 11–983 | Decadron Topical Cream | Merck & Co., Inc. |
| NDA 12–108 | Vaga Spray | Menlo Park Laboratories, Inc., 459 Amboy Ave., P.O. Box 648, Woodbridge, NJ 07095. |
| NDA 12–311 | Pentritol (pentaerythritol tetranitrate) Timed Release Tempules 60 mg. | Rhône-Poulenc Rorer Pharmaceuticals Inc., 500 Arcola Rd., P.O. Box 1200, Collegeville, PA 19426–0107. |
| NDA 12–487 | Taractan (chlorprothixene Ampuls) | Hoffmann-La Roche, Inc., 340 Kingsland St., Nutley, NJ 07110–1199. |
| NDA 16–219 | Lemon Spree Deodorant Soap | Colgate-Palmolive Co., 909 River Rd., P.O. Box 1343, Piscataway, NJ 08855–1343. |
| NDA 16–264 | Palmolive Gold Antibacterial Deodorant Soap | Do. |
| NDA 16–278 | Tackle Medicated Soap | Do. |
| NDA 16–457 | Pentritol (pentaerythritol tetranitrate) Timed Release Tempules 30 mg. | Rhône-Poulenc Rorer Pharmaceuticals Inc. |
| NDA 16–486 | P–300 Antibacterial Deodorant Soap | Colgate-Palmolive Co. |
| NDA 16–818 | Emete-con (benzquinmide HCl) Suppositories | Pfizer, Inc. |
| NDA 17–818 | HALOG (halcinonide) Cream, 0.025% | Westwood-Squibb Pharmaceuticals Inc., 100 Forest Ave., Buffalo, NY 114213–1091. |
| NDA 17–914 | OTIC-TRIDESILON (desonide-acetic acid) Solution, 0.05% | Bayer Corp., 400 Morgan Lane, West Haven, CT 06516–4175 |
| NDA 18–040 | Monistat (miconazole) i.v. | Janssen, 1125 Trenton-Harbourton Rd., P.O. Box 200, Titusville, NJ 08560–0200. |
| NDA 18–793 | Cold Capsule IV (phenyl-propanolamine hydro-chloride 75 mg and chlorpheniramine maleate 12 mg extended-release capsules). | D. M. Graham Laboratories, Inc., 58 Pearl St., Hobart, NY 13788. |
| NDA 18–794 | Cold Capsule V (phenylpropanolamine hydrochloride 75 mg and chlorpheniramine maleate 8 mg extended-release capsules). | Do. |
| NDA 18–843 | Pseudoephrine hydrochloride 120 mg and chlorpheniramine maeleate 12 mg extended-release capsules. | Do. |
| NDA 18–844 | Pseudoephredrine hydrochloride 120 mg and chlorpheniramine mealeate 8 mg extended-release capsules. | Do. |
| NDA 50–165 | Polysporin Ointment | Burroughs Wellcome Co., 3030 Cornwallis Rd., P.O. Box 12700, Research Triangle Park, NC 27709–2700. |
| NDA 50–166 | Polysporin Topical Powder | Do. |
| NDA 50–170 | Neosporin Ointment | Do. |
| NDA 50–313 | Fungizone Ointment | Apothecon, P.O. Box 4500, Princeton, NJ 08543–4500. |
| NDA 50–323 | NEODECADRON Topical Cream | Merck &. Co., Inc. |
| NDA 50–325 | NEODECASPRAY Topical Aerosol | Do. |
| NDA 50–459 | Amoxil (amoxicillin trihydrate) capsules | SmitheKline Beecham, One Franklin Plaza, P.O. Box 7929, Philadelphia, PA 19101. |
| NDA 50–460 | Amoxicillin trihydrate for oral suspension | Do. |
| NDA 50–601 | Ceradon (Cefotiam HCl for Injection) | Takeda Chemical Industries Ltd. c/o Corning Besselaar, Inc., 210 Carnegie Center, Princeton, NJ 08540–6233. |
| NDA 50–678 | DYNABAC (dirithromycin tablets) | Lilly Research Laboratories, Lilly Corporate Center, Indianapolis, IN 46285. |
| AADA 60–095 | Tetracycline Suspension 100 mg/mL and Tetracycline Suspension 125 mg/5 mL. | Pfizer, Inc. |
| AADA 60–199 | Chloramphenicol Palmitate USP (nonsterile bulk) | Chong Kun Dang Corp., 14 Magnet St., Stony Brook, NY 11790. |
| AADA 60–200 | Chloramphenicol USP, non-sterile bulk | Do. |
| AADA 60–285 | Tetracycline Hydrochloride Intramuscular Injection, 100 mg and 250 mg vials (both with Procaine Hydrochloride 2%). | Pfizer, Inc. |
| AADA 60–436 | Chloraphenicol Sodium Succinate USP, (Sterile bulk) | Chong Kun Dang Corp. |
| AADA 61–606 | Pyocidin-Otic (Polymyxin B Sulfate and Hydrocortisone Otic Solution USP); 10,000 units and 5 mg/mL). | Forest Laboratories, Inc., 909 Third Ave., New York, NY 10022–4731. |
| AADA 62–077 | Ampicillin Anhydrous (bulk) | Sandoz Pharmaceutical, Agent for Roferm S.p.A., 59 Route 10, East Hanover, NJ 07936–1080. |

| Application No. | Drug | Applicant |
|---|---|---|
| AADA 62–174 | Erythromycin Ethylsuccinate, USP (nonsterile bulk) | Pharmacia & Upjohn, 7000 Portage Rd., Kalamzoo, MI 49001–0199. |
| AADA 62–301 | Chloramphenacol Palmitate Suspension USP, 150 mg/5 mL. | Parke-Davis. |
| AADA 62–647 | Amoxicillin Trihydrate (bulk) | Sandoz Pharmaceuticals, Agent for Roferm S.p.A. |
| AADA 62–794 | Clindamycin Phosphate USP, nonsterile bulk | Biochimica Opos S.p.A., c/o Kleinfeld, Kaplan, and Becker, 1140 Nineteenth St. NW., suite 900,Washington, DC 20036. |
| AADA 63–130 | Minocycline Hydrochloride (bulk, nonsterile) | Do. |
| AADA 64–072 | Cefaclor USP, (bulk, nonsterile) | Do. |
| ANDA 70–516 | Propranolol Hydrochloride Tablets USP, 10 mg | Roxane Laboratories, Inc., P.O. Box 16532, Columbus, OH 43216–6532. |
| ANDA 70–517 | Propranolol Hydrochloride Tablets USP, 20 mg | Do. |
| ANDA 70–518 | Propranolol Hydrochloride Tablets USP, 40 mg | Do. |
| ANDA 70–519 | Propranolol Hydrochloride Tablets USP, 60 mg | Do. |
| ANDA 70–521 | Propranolol Hydrochloride Tablets USP, 90 mg | Do. |
| ANDA 71–555 | Nitropress (Sterile Sodium Nitroprusside, USP) 50 mg vial | Abbott Laboratories, D–389 Bldg., AP30, 200 Abbott Park Rd., Abbott Park, IL 60064–3537. |
| ANDA 80–368 | Isoniazid Tablets USP, 50 mg and 100 mg | Vintage Pharmaceuticals, Inc., 3241 Woodpark Blvd., Charlotte, NC 28206. |
| ANDA 80–778 | Hydroxcobalamin Injection (Alpha Redisol) | Merck & Co., Inc. |
| ANDA 83–089 | Propoxyphene Hydrochloride Capsules USP, 65 mg | Roxane Laboratories, Inc. |
| ANDA 84–772 | Promethazine Hydrochloride Syrup USP, 25 mg/5 mL | Alpharma, U.S. Pharmaceuticals Division, 333 Cassell Dr., suite 3500, Baltimore, MD 21224. |
| ANDA 85–169 | Theophylline Elixir, 80 mg/15 mL | Halsey Drug Col, Inc., 1827 Pacific St., Brooklyn, NY 11233–3599. |
| ANDA 85–263 | Theophylline Capsules, 100 mg and 200 mg | KV Pharmaceutical Co., 2503 South Hanely Rd., St. Louis, MO 63144–2555. |
| ANDA 85–364 | Acetaminophen and Codeine Phosphate Tablets, USP (300 mg/15 mg). | Do. |
| ANDA 85–365 | Acetaminophen and Codeine Phosphate Tablet, USP (300 mg/60 mg). | Do. |
| ANDA 85–523 | Meclinzine Hydrochloride Tablets USP, 25 mg | Do. |
| ANDA 85–524 | Meclizine Hydrochloride Tablets USP, 12.5 mg | Do. |
| ANDA 85–525 | Phendimetrazine Tartrate Tablets USP, 35 mg | Do. |
| ANDA 85–555 | Cyclopentolate Hydrochloride Opthalmic Solution USP, 1% | Akorn Manufacturing, Inc. |
| ANDA 85–658 | Methocarbamol Tablets, USP (705 mg) | KV Pharmaceutical Co. |
| ANDA 85–659 | Diphenoxylate Hydrochloride and Atropine Sulfate Tablets USP, 2.5 mg/0.25 mg. | Do. |
| ANDA 85–660 | Methocarbamol Tablets, USP (500 mg) | Do. |
| ANDA 86–264 | Ergoloid Mesylates Sublingual Tablets (1.0 mg) | Do. |
| ANDA 86–265 | Ergoloid Mesylates Sublingual Tablets (0.5 mg) | Do. |
| ANDA 86–737 | Cyproheptadine Hydrochloride Tablets USP, 4 mg | KV Pharmaceutical Co. |
| ANDA 86–760 | Phyllocontin (Aminophylline Controlled-release Tablets), 225 mg. | The Perdue Frederick Co., 100 Connecticut Ave., Norwalk, CT 06850–3590. |
| ANDA 87–164 | Chlorpheniramine Maleate Tablets USP, 4 mg | Do. |
| ANDA 87–193 | Theophylline Extended-release Capsules, 250 mg | D. M. Graham Laboratories, Inc. |
| ANDA 87–194 | Theophylline Extended-release Capsules, 100 mg | Do. |
| ANDA 87–195 | Diphenoxylate Hydrochloride with Atropine Sulfate Tablets, 2.5 mg/0.025 mg. | ICN Pharmaceuticals, Inc., ICN Plaza, 3300 Hyland Ave, Costa Mesa, CA 92626. |
| ANDA 87–243 | Aminophyllin Injection, USP | G. D. Searle and Co., 4901 Searle Pkwy., Skokie, IL 60077. |
| ANDA 87–464 | Oxycodone and Aspirin Tablets, 4.5 mg/235 mg | Halsey Drug Co., Inc. |
| ANDA 87–763 | Theophylline Extended-release Capsules, 50 mg | D.M. Graham Laboratories, Inc. |
| ANDA 88–020 | Trimcaps (Phendimetrazine Tartrate Extended-release Capsules, 105 mg). | Do. |
| ANDA 88–028 | Dital (Phendimetrazine Tartrate Extended-release Capsules, 105 mg). | Do. |
| ANDA 88–063 | Dyrexan-OD (Phendimetrazine Tartrate Extended-release Capsules, 105 mg). | Do. |
| ANDA 88–111 | Rexigen Forte (Phendimetrazine Tartrate Extended-release Capsules, 105 mg). | Do. |
| ANDA 88–377 | Propantheline Bromide Tablets, 15 mg | Par Pharmaceutical, Inc., One Ram Ridge Rd., Spring Valley, NY 10977. |
| ANDA 88–382 | Theophylline Extended-release Capsules, 200 mg | D. M. Graham Laboratories, Inc. |
| ANDA 88–383 | Theophylline Extended-release Capsules, 300 mg | Do. |
| ANDA 88–577 | Hydrocodone Bitartrate and Acetaminophen Tablets USP, 5 mg/500 mg. | Barr Laboratories, Inc., Two Quaker Rd., P.O. Box 2900, Pomona, NY 10970–0519. |
| ANDA 88–689 | Theophylline Extended release Capsules USP, 250 mg | Central Pharmaceutical, Inc., 120 East Third St., Seymour, IN 47274–0328 |
| ANDA 88–743 | Endolor (Butalbital, Acetaminophen, and Caffeine Capsules USP, 50 mg/325 mg/40 mg. | D. M. Graham Laboratories, Inc. |

| Application No. | Drug | Applicant |
|---|---|---|
| ANDA 88–765 ..... | Two-Dyne (Butalbital, Acetaminophen, and Caffeine Capsules USP, 50 mg/325 mg/40 mg. | Do. |
| ANDA 89–067 ..... | Margesic (Butalbital, Acetaminophen, and Caffeine Capsules USP, 50 mg/325 mg/40 mg. | Do. |
| ANDA 89–605 ..... | Prochlorperazine Edisylate Injection USP, 5 mg/mL ..... | Steris Laboratories, Inc., 620 North 51st Ave., Pheonix, AZ 85040–4705. |
| ANDA 89–994 ..... | Oxycodone Hydrochloride and Acetaminophen Capulses, 5 mg/500 mg. | Halsey Drug Co., Inc. |

NDA's 8–072, 11–983, 12–311, and 16–457 were the subject of a hearing (Docket No. 87N–0262 (52 FR 32170, August 26, 1987)). The initial decision of the Administrative Law Judge (ALJ) was that the drug products covered by the NDA's lacked substantial evidence of effectiveness. The holder of NDA's 12–311 and 16–457 was stricken as a party participant in the hearing for failure to file a notice of participation, and the holder of NDA's 8–072 and 11–983 has formally withdrawn its appeal of the initial decision of the ALJ. This notice, therefore, constitutes final agency action on Docket No. 87N–0262 insofar as these four NDA's.

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) approval of the applications listed in the table in this document, and all amendments and supplements thereto, is hereby withdrawn, effective July 25, 1997.

Dated: June 17, 1997.

**William K. Hubbard,**

*Associate Commissioner for Policy Coordination.*

[FR Doc. 97–16609 Filed 6–24–97; 8:45 am]

**BILLING CODE 4160–01–F**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

**[HCFA–R–54 and HCFA–250]**

### Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summaries of proposed collections for public comment. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Ambulatory Surgical Center Conditions of Coverage and Supporting Regulations in 42 CFR 416.43 and 416.47; *Document No.:* HCFA–R–54; *Use:* Regulation standards are designed to ensure that each Ambulatory Surgical Center has a properly trained staff and adequate physical environment to provide an appropriate type and level of care. *Frequency:* Annually; *Affected Public:* Business or other for-profit; *Number of Respondents:* 2,341; *Total Annual Hours:* 23,410.

2. *Type of Information Collection Request:* Reinstatement, without change, of a previously approved collection for which approval has expired; *Title of Information Collection:* Medicare Secondary Payer Initial Enrollment Questionnaire; *Form No.:* HCFA 250; *Use:* This request will be mailed to all newly enrolled Medicare Beneficiaries approximately 1 to 3 months prior to his/her entitlement date. The information requested will determine if Medicare is the proper primary payer, or if the beneficiary is covered under an employer group health plan through continuation of employment after age 65, or through coverage of a currently employed spouse. This centralizes and standardizes the collection of information under one contract. *Frequency:* Other—Monthly for New Beneficiaries Only; *Affected Public:* Individual or Households; *Number of Respondents:* 2,600,000; *Total Annual Hours:* 650,000.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access HCFA's WEB SITE ADDRESS at http://www.hcfa.gov/regs/prdact95.htm, or to obtain the supporting statement and any related forms, E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Financial and Human Resources, Management Analysis and Planning Staff, Attention: Louis Blank, Room C2–26–17, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: June 16, 1997.

**Edwin J. Glatzel,**

*Director, Management Analysis and Planning Staff, Office of Financial and Human Resources.*

[FR Doc. 97–16602 Filed 6–24–97; 8:45 am]

**BILLING CODE 4120–03–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

**[416]**

### Submitted for Collection of Public Comment: Submission for OMB Review

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposals for the collection of information. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of