received on or before October 20, 1980, and should be addressed to Mr. John M. Lovelady, Senior Group Director, Regulatory Reports Review, United States General Accounting Office, Room 5106, 441 G Street, NW, Washington, DC 20548.

Further information may be obtained from Patsy J. Stuart of the Regulatory Reports Review Staff, 202–275–3532.

Nuclear Regulatory Commission

The NRC requests an extension without change of the application, reporting and recordkeeping requirements contained in 10 CFR Part 55, Operator's License. Specifically, § 55.10(a) which sets forth the information that must be contained in an application for a nuclear facilities operator's license; § 55.33 which sets forth the requirements for renewal applications for an operator's license; § 55.41 which requires the licensed operator to notify the NRC of any disability which occurs after the submission of his medical certificate; and Appendix A which requires periodic requalification program records be kept to document each licensed operator's or senior operator's participation in the program. The NRC estimates that time to prepare an application under § 55.10(a) will require 1.5 hours and approximately 1,800 will be filed annually; to prepare a renewal application under § 55.33 will require 1.5 hours and approximately 900 will be filed annually; to prepare a notification to NRC of a disability under § 55.41 will require 15 minutes and approximately 15 are expected to be filed annually; and to keep records for the requalification program under Appendix A will require 15 minutes for each record and records are expected to number 900.

Norman F. Heyl,

Regulatory Reports, Review Officer.

[FR Doc. 80-30177 Filed 9-29-80; 8:45 am]

BILLING CODE 1610-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

CENTER FOR DISEASE CONTROL

Mine Health Research Advisory Committee; Meeting

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Center for Disease Control announces the following National Institute for Occupational Safety and Health Committee meeting:

Name: Mine Health Research Advisory Committee.

Date: October 30–31, 1980.

Place: Lakeview Inn, Route 6, Morgantown, W. Va. 26505.

Time: 9 a.m.–5:30 p.m., October 30. 8 a.m.–12:30 p.m., October 31.

Type of Meeting: Closed: 9 a.m. to 11:30 a.m. on October 30. Open 1 p.m. on October 30 through adjournment on October 31.

Contact Person: Roy M. Fleming, Sc.D., Executive Secretary, 5600 Fishers Lane, Room 8A–44, Rockville, Md. 20857, Phone: (301) 443–4614.

Purpose: The Committee is charged with advising the Secretary of Health and Human Services on matters involving or relating to mine health research, including grants and contracts for such research.

Agenda: Beginning at 9 a.m. on October 30, the Committee will be performing the final review of the mine health research grant applications for Federal assistance. This portion of the meeting will not be open to the public in accordance with the provisions set forth in Section 552(c)(6), Title 5 U.S. Code and the Determination of the Director, Center for Disease Control, pursuant to Public Law 92–463.

Agenda items for the open portion of the meeting beginning at 1 p.m. on October 30 will include announcements, consideration of minutes of previous meeting and future meeting dates, presentations and discussions on the National Institute for Occupational Safety and Health (NIOSH) program planning process, NIOSH mine research plan and priorities, Bureau of Mines research impacting on health issues, NIOSH response to health hazard evaluation recommendations by the Committe, benzene and lead court decisions, considerations for small population studies, and reports on personal protective equipment and safety workshops.

Agenda items are subject to change as priorities dictate.

The portion of the meeting so indicated is open to the public for observation and participation. Anyone wishing to make an oral presentation should notify the contact person listed above as soon as possible before the meeting. The request should state the amount of time desired, the capacity in which the person will appear, and a brief outline of the presentation. Oral presentations will be scheduled at the discretion of the Chairperson and as time permits. Anyone wishing to have a question answered during the meeting by a scheduled speaker should submit the question in writing, along with his or her name and affiliation, through the Executive Secretary to the Chairperson. At the discretion of the Chairperson and as time permits, appropriate questions will be asked of the speakers.

A roster of members and other relevant information regarding the meeting may be obtained from the contact person listed above.

Dated: September 24, 1980.

William H. Foege, M.D.,

Director, Center for Disease Control.

[FR Doc. 80-30414 Filed 9-29-80; 8:45 am]

BILLING CODE 4110-87-M

Food and Drug Administration

[Docket No. 76N-0052]

Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter (OTC) Human Use; Decision on Dosage of Pseudoephedrine Preparations

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration is issuing a notice announcing the decision to reduce the dosage of pseudoephedrine preparations (pseudoephedrine hydrochloride and pseudoephedrine sulfate) in the proposed monograph for OTC oral nasal decongestants. This notice also states the agency's interim marketing policy on products containing pseudoephedrine.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Bureau of Drugs (HFD–510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4960.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 9, 1976 (41 FR 38312), the Commissioner of Food and Drugs issued the recommendations and proposed monograph of the Advisory Review Panel on OTC Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products. These recommendations included a determination that pseudoephedrine (pseudoephedrine hydrochloride and pseudoephedrine sulfate) is generally recognized as safe and effective (Category I) for OTC use as an oral nasal decongestant. (See 41 FR 38402.) The Panel recommended an adult oral dosage of 60 milligrams (mg) every 4 hours not to exceed a maximum of 360 mg in 24 hours. This dosage schedule was included in § 341.20(g) of the proposed monograph. (See 41 FR 38420.)

On December 1, 1976, The Dow Chemical Co. submitted data to support the company's request that the Category I adult oral dosage of pseudoephedrine be reduced to 60 mg every 4 to 6 hours not to exceed a maximum of 240 mg in 24 hours (Ref. 1). The company presented data which demonstrated that the half-life of pseudoephedrine is 7 to 8 hours following a 60 mg dose and that a 6-hour dosing schedule will maintain the serum concentration of pseudoephedrine above the peak level achieved following the first single dose (Ref. 2). A study by Bye, Hughes, and Peck (Ref. 3) demonstrated a similar half-life of the 60 mg dosage. Dow Chemical Co. concluded that the data suggest that a maximum dose of 240 mg in 24 hours is a

more appropriate OTC dose than a maximum dose of 360 mg in 24 hours.

Bye, Hughes, and Peck (Ref. 3) also found that a dose of 60 mg pseudoephedrine produced a slight (but not statistically significant) rise in pulse rate which was still evident at 4.5 hours after the first dose and at 6 hours after the second dose. The second dose was given 4.5 hours after the first dose. This would suggest that if another 60 mg had been given at 4 hours after the second dose (as would occur with the Panel's proposed dosage of 60 mg every 4 hours), the pulse rate would have been still higher. This study also demonstrated that when 180 mg of pseudoephedrine in a sustained release dosage form was given twice daily for 14 days, there was a significant increase in heart rate and insomnia for the first 3 days.

Dickerson et al. (Ref. 4) found that 150 mg sustained-release pseudoephedrine taken twice daily caused a greater increase in pulse rate than 120 mg sustained-release pseudoephedrine and that only the higher dose had a significant effect on systolic pressure. Both doses, however, caused a similar incidence of insomnia.

McLaurin, Shipman, and Rosedale (Ref. 5) studied 88 subjects given a single 60-mg dose of pseudoephedrine. Blood pressure, heart rate, subjective responses, and changes in nasal airway obstruction as measured by a rhinometric technique were monitored. No significant differences in any of the measured parameters were apparent. Subjective complaints of nervousness were noted. Multiple-dose studies were not carried out.

Empey et al. (Ref. 6) gave pseudoephedrine 60 mg three times daily for 2 weeks to 40 volunteers with gross pollinosis. Subjective symptom scores were recorded. Pseudopehedrine in a dose of 180 mg daily was significantly effective in reducing symptoms, while side effects were minimal.

Benson (Ref. 7) measured the oral and nasal maximal inspiratory flow rates in eleven volunteers with intermittent nasal obstruction who were given placebo or 60 mg pseudoephedrine in single doses. The study demonstrated that a single dose of drug was followed by significant increase in nasal flow rates lasting up to 2 hours. Multiple dose studies were not done.

References

(1) Dow Chemical Co., Comment submitted on Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic proposed monograph (C–0112) is on file at the Hearing Clerk's office under docket number 76N–0052.

(2) Carski, T. R., "Three-Way Cross Over Study: Comparison of Blood Levels of Pseudoephedrine HCL Following Single Oral Doses of a 120 mg Sustained-Release Formulation with Those Following a Single Oral Dose of a 120 mg Immediate-Release Formulation and with the Levels Following Two Oral Doses of a 60 mg Immediate-Release Formulation," Summary of unpublished study is included in C–0112 cited in Reference (1) above.

(3) Bye, H. M., D. T. D. Hughes, and A. W. Peck, "Comparison of Plasma Levels of L(+) Pseudoephedrine Following Different Formulations, and Their Relation to Cardiovascular and Subjective Effects in Man," *European Journal of Clinical Pharmacology,* 8:47–53, 1975.

(4) Dickerson, J., et al., "Dose Tolerance and Pharmacokinetic Studies of L(+) Pseudoephedrine Capsules in Man," *European Journal of Clinical Pharmacology,* 14:253–259, 1978.

(5) McLaurin, J. W., W. F. Shipman, and R. Rosedale, Jr., "Oral Decongestants. A Double-Blind Comparison Study of the Effectiveness of Four Sympathomimetic Drugs: Objective and Subjective," *Laryngoscope,* 71:54–67, 1961.

(6) Empey, D. W., et al., "A Double-Blind Crossover Trial of Pseudoephedrine and Triprolidine, Alone and in Combination, for the Treatment of Allergic Rhinitis," *Annals of Allergy,* 34:41–46, 1975.

(7) Benson, M. K., "Maximal Nasal Inspiratory Flow Rate: Its Use in Assessing the Effect of Pseudoephedrine in Vasomotor Rhinitis," *European Journal of Clinical Pharmacology,* 3:182–184, 1971.

The agency concludes that the above data do not support the Panel's recommendation for a 360 mg daily dose of pseudoephedrine. In fact, the Carski study (Ref. 2) suggests that a strict 4 hour dosage of 60 mg might lead to accumulation of the drug and eventually marked side effects. The data do, however, support the 60 mg dosage. The data from the studies also suggest that a daily dosage in excess of 240 mg of pseudoephedrine may be associated with significant side effects without additional therapeutic benefit. Therefore, the agency concludes that there are sufficient data to support a 60 mg dose of pseudoephedrine every 6 hours with a maximum 24 hour dose of 240 mg. The agency also points out that the Panel recommended an oral dosage for pseudoephedrine preparations for children 6 to under 12 years of age of 30 mg every 4 hours not to exceed 180 mg in 24 hours and for children 2 to under 6 years of age of 15 mg every 4 hours not to exceed 90 mg in 24 hours. These maximum daily dosages are one-half and one-quarter of the adult maximum daily dose. Along with the reduction in the adult maximum daily dose to 240 mg, the agency is also reducing the dosages for children proportionately. The new dosage for children 6 to under 12 years of age will be 30 mg every 6 hours not to exceed 120 mg in 24 hours and for children 2 to under 6 years of age will be 15 mg every 6 hours not to exceed 60 mg in 24 hours.

The OTC drug review regulations in § 330.13 (21 CFR 330.13) state the conditions for marketing on OTC drug product containing an active ingredient at a dosage level higher than that available in an OTC drug product on December 4, 1975, which an OTC Advisory Review Panel has recommended for OTC use. These regulations allow the OTC marketing of such a product at the higher dosage level after the date of publication in the **Federal Register** of the Panel's report and proposed monograph, subject to the risk that the Commissioner may not accept the Panel's recommendation and may instead adopt a different position that may require relabeling, recall, or other regulatory action. The OTC marketing of products containing pseudoephedrine labeled with a 60-mg single dose or a maximum daily dose of 360 mg represents marketing of an active ingredient at a dosage level higher than that available in an OTC drug product on December 4, 1975. Under the provisions of § 330.13(b)(2), such products labeled in accord with the proposed monograph may be marketed unless the Commissioner adopts and announces a different position. In this notice, the Commissioner is announcing that he does not, at this time, accept the recommendation of the Advisory Review Panel on OTC Cold, Cough, Allergy, Bronchodilator and Antiasthmatic Products on the dosage of drug products containing pseudoephedrine for OTC use as an oral nasal decongestant. As provided under § 330.13(b)(2), the Commissioner has concluded that OTC drug products marketed for use as an oral nasal decongestant containing pseudoephedrine at a dosage level higher than that available in an OTC drug product on December 4, 1975 are required to be labeled with the following dosage limitations:

Adult oral dosage is 60 mg every 6 hours not to exceed 240 mg in 24 hours. For children 6 to under 12 years of age, the oral dosage is 30 mg every 6 hours not to exceed 120 mg in 24 hours. For children 2 to under 6 years of age, the oral dosage is 15 mg every 6 hours not to exceed 60 mg in 24 hours. For children under 2 years of age, there is no recommended dosage except under the advice and supervision of a physician.

Therefore, in accordance with § 330.13(b)(2), any OTC oral nasal decongestant drug product containing pseudoephedrine at a dosage level higher than that available in an OTC drug product on December 4, 197[illegible] required to be labeled with thi[illegible]

lower dosage. To avoid disruption of the OTC cough-cold market, firms will be allowed up to 4 months, until January 30, 1981 to relabel their OTC oral nasal decongestant drug products containing pseudoephedrine. Manufacturers are encouraged, however, to implement this change in the labeling of currently marketed products containing pseudoephedrine at the earliest possible time. After January 30, 1981, no further shipments of OTC oral nasal decongestant drug products containing pseudoephedrine labeled with the former higher dosage can be initially introduction or initially delivered for introduced into interstate commerce.

The agency will include these revised dosages for pseudoephedrine preparations in the tentative final monograph on OTC nasal decongestant drug products. The agency intends to issue the tentative final monograph for OTC Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products in segments. The first segment will be on anticholinergics and expectorants. Subsequent sections will be published on antihistamines, nasal decongestants, antitussives, bronchodilators, and combinations. A final determination of the appropriate dosage limitations for OTC pseudoephedrine preparations will be made in the final monograph for these OTC nasal decongestant drug products.

Dated: September 22, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-29912 Filed 9-29-80; 8:45 am]

BILLING CODE 4110-03-M

[Docket No. 80D-0217]

General Statistical Documentation Guide for Protocol Development of NDA Submissions, Availability of Draft Guideline; Extension of Comment Period

AGENCY: Food and Drug Administration.

ACTION: Extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending the period for submitting comments on the draft guideline entitled "General Statistical Documentation Guide for Protocol Development and NDA Submissions." This action is in response to a request by the Pharmaceutical Manufacturers Association for additional time to consider the draft guideline and prepare comments. FDA believes it is in the public interest to delay final preparation of the guideline until the Pharmaceutical Manufacturers Association's comments can be reviewed.

DATE: Written comments by December 6, 1980.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Satya D. Dubey, Bureau of Drugs (HFD-232), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4594.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 8, 1980 (45 FR 45961), FDA announced the availability of a draft guideline entitled "General Statistical Documentation Guide for Protocol Development and NDA Submission," prepared by FDA's Bureau of Drugs, which sets forth the type of material needed to permit statistical review of protocols and completed clinical studies by the agency. Interested persons were given until October 6, 1980, to submit written comments on the guideline. In response to a request from the Pharmaceutical Manufacturers Association, FDA is extending the comment period for all interested persons until December 6, 1980.

Interested persons may, on or before December 6, 1980, submit written comments on the draft guideline to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857. Those comments will be considered in determining whether further amendments to or revisions of the guideline are warranted. Comments should be in four copies (except that individuals may submit single copies), identified with the Hearing Clerk docket number found in brackets in the heading of this document. The draft guideline and received comments may be seen in the Hearing Clerk's office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 23, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-30207 Filed 9-26-80; 9:55 am]

BILLING CODE 4110-03-M

Public Health Service

Privacy Act of 1974; New System of Records

AGENCY: Department of Health and Human Services; Public Health Service.

ACTION: Waiver of advance notice period for a new system of records.

SUMMARY: FR Doc. 80-26614, appearing at page 58209 in the issue for Tuesday, September 2, 1980, provided notification of a new system of records proposed by the Health Resources Administration. That system is 09-35-0045, "Nurse Practitioner Traineeships," HHS/HRA/BHPr. The document stated that the Public Health Service (PHS) had requested that the Office of Management and Budget (OMB) grant a waiver of the usual requirement that a system of records not be put into effect until 60 days after the report is sent to OMB and Congress.

OMB granted the requested waiver on September 12, 1980. Accordingly, system of records number 09-35-0045 became effective upon the date of the waiver. However, PHS will not disclose information from this system pursuant to a routine use until after the period for public comment on proposed routine uses elapses on October 2, 1980.

Dated: September 23, 1980.

Jack N. Markowitz,

Acting Director, Office of Management.

[FR Doc. 30-199 Filed 9-29-80; 8:45 am]

BILLING CODE 4110-85-M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Community Planning and Development

[Docket No. N-80-1028]

Community Development Block Grant Program for Indian Tribes and Alaskan Natives

AGENCY: Housing and Urban Development/Office of the Assistant Secretary for Community Planning and Development.

ACTION: Notice.

SUMMARY: This notice sets the deadline for filing pre-applications for Community Development Block Grant Funds for Indian Tribes and Alaskan Natives for Fiscal Year 1981. Pre-applications are required in order to provide HUD with sufficient information to determine which applicants will be invited to submit full application and to save applicants the cost of preparing full applications which have no chance of being funded.

SUPPLEMENTARY INFORMATION: This notice sets the deadline for submitting pre-applications as provided in 24 CFR 571.301 published by final rule on December 15, 1978 (43 FR 58734). That rule established Part 571 as a separate part applying the Community Development Block Grant Program to