accounting principles and standards consistently applied, except as otherwise expressly required by instructions for reports of condition and income.

§ 334.3 General principles applicable to contracts.

(a) No person may enter into or perform or accept any benefit under an adverse contract. Whether a particular contracts is adverse shall be determined on the basis of, among other criteria, its own terms and a comparison with the terms of similar contracts entered into by the institution and by other institutions, taking into account any other contract or financial relationship entered into by or on behalf of the institution which directly or indirectly involves the same or related parties.

(b) A contract would be adverse, by way of example and not in limitation of the foregoing, if it provides or allows for termination, cancellation or rescission by the person dealing with an institution and fails expressly to provide the institution (including its successor, receiver or conservator) with sufficient reasonable prior notice (including any necessary information and materials, *e.g.*, computer programs and related documentation, data files, and machine-readable tapes) and an opportunity to provide for substitute or replacement goods, products or services at fair market terms consistent with safety and soundness,[1] or if the contract requires an unreasonable period of prior notice of termination by the institution.

§ 334.4 Burden of proof.

In any examination or other supervisory proceeding where the appropriate federal banking agency initially has made a determination that an institution has entered into an adverse contract in violation of 12 U.S.C. 1831g and this part, and in any administrative enforcement proceeding where such an agency initially has made a showing to that effect, the institution and other contracting parties involved in the proceeding shall be required to demonstrate the propriety and legality of the contract hereunder by establishing that, under all the relevant circumstances, the contract is not an adverse contract.

[1] In this connection, 12 U.S.C. 1821(e)(12)(A) authorizes the FDIC as conservator or receiver to "enforce any contract, other than a director's or officer's liability insurance contract or a depository institution bond, entered into by the depository institution notwithstanding any provision of the contract providing for termination, default, acceleration, or exercise of rights upon, or solely by reason of, insolvency or the appointment of a conservator or receiver."

§ 334.5 Enforcement.

Institutions and institution-affiliated parties, including any independent contractor, may be subject to removal and/or prohibiton orders, cease and desist orders, and the imposition of civil money penalties pursuant to section 8 of the Federal Deposit Insurance Act (12 U.S.C. 1818), as amended, for violation of this part, as well as any other action or remedy authorized by law.

By order of the Board of Directors.

Dated at Washington, DC, this 26th day of March 1991.

Federal Deposit Insurance Corporation.

Hoyle L. Robinson,

Executive Secretary.

[FR Doc. 91-7549 Filed 3-29-91; 8:45 am]

BILLING CODE 6714-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 357

[Docket No. 81N-0022]

RIN 0905-AA06

Phenylpropanolamine Hydrochloride for Over-the-Counter Weight Control Use; Safety and Effectiveness Discussion; Public Meeting and Reopening of the Administrative Record

AGENCY: Food and Drug Administration, HHS.

ACTION: Public meeting and reopening of the administrative record.

SUMMARY: The Food and Drug Administration (FDA) is reopening the administrative record and announcing that a public meeting will be held to discuss the safety and effectiveness of phenylpropanolamine hydrochloride for over-the-counter (OTC) weight control use. One part of the discussion will include possible misuse of the drug. The meeting is part of the ongoing review of OTC drug products conducted by FDA and will be structured to discuss the specific topics and to seek answers to the specific questions listed in this notice.

DATES: The meeting will be held on May 9, 1991, at 8:30 a.m. The agency anticipates that the meeting will last 1 day. However, if there is sufficient interest in participation, the meeting will be extended an additional day at the discretion of the chairperson. Relevant data and notice of participation by May 1, 1991. Administrative record to remain open until August 7, 1991. Comments regarding matters raised at the meeting by August 7, 1991.

ADDRESSES: Relevant data, notice of participation, and written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857. Meeting to be held in Conference Rm. E, Parklawn Bldg., 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Helen Cothran or Mary Robinson, Center for Drug Evaluation and Research (HFD-210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8006.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 26, 1982 (47 FR 8466), FDA published an advance notice of proposed rulemaking on OTC weight control drug products based on the recommendations and the report of the Advisory Review Panel on OTC Miscellaneous Internal Drug Products (the Panel). In that report, the Panel recommended that single doses of 25 to 50 milligrams (mg) and a total daily dose of not more than 150 mg of phenylpropanolamine hydrochloride be generally recognized as safe and effective in an OTC drug product for weight control use. However, in the preamble to the Panel's report, the agency limited the Panel's recommended dosage of phenylpropanolamine hydrochloride for OTC weight control use to the level present in products marketed as of December 4, 1975, i.e., a maximum daily dose of 75 mg, immediate release doses of 25 to 37.5 mg, and a timed-release (over 12 to 16 hours) dose of 75 mg of phenylpropanolamine hydrochloride. The Panel further recommended that OTC weight control drug products bear the statement, "This product's effectiveness is directly related to the degree to which you reduce your usual daily food intake. Attempts at weight reduction which involve the use of this product should be limited to periods not exceeding three months, because that should be enough time to establish new eating habits."

Reports, which became available after the Panel completed its evaluation, indicated that phenylpropanolamine hydrochloride doses higher than those currently marketed caused elevation of blood pressure. Therefore, in the preamble to the Panel's report (47 FR 8466), the agency requested comments and information to resolve the safety questions raised in these reports. The agency has received numerous data and comments regarding the safety and effectiveness of phenylpropanolamine

hydrochloride. These data and comments are on public display in the Dockets Management Branch under Docket No. 81N–0022.

As the agency was completing its review of the data and information submitted to this rulemaking on OTC weight control drug products, the House Small Business Subcommittee on Regulation, Business Opportunities, and Energy, chaired by Congressman Ron Wyden, held a hearing on September 24, 1990, to examine adolescent dieting behavior, diet pills containing phenylpropanolamine hydrochloride, and Federal research efforts on obesity. In a letter sent to FDA on September 26, 1990 (Ref. 1), Chairman Wyden stated that witnesses had presented very disturbing testimony about the misuse of phenylpropanolamine diet pills at the hearing, as follows:

1. A new epidemiological study demonstrates that phenylpropanolamine hydrochloride OTC preparations of all types lead all other OTC remedies in both number of serious and fatal adverse effects in people under 29 years old, as well as in number of contacts with Poison Control Centers each year.

2. New clinical trials confirm statistically significant increases in blood pressure in study subjects, corroborating the evidence of increased reactions in the population at large.

3. The majority of purchasers misuse the drug and do not follow the current label instructions or indications.

4. The majority of users find phenylpropanolamine hydrochloride to be ineffective.

5. Phenylpropanolamine hydrochloride diet pills have become a primary pathological pathway in the deterioration of patients with anorexia nervosa.

6. New research on obesity documents the deleterious effects of diet practices that cause rebound or yo-yo weight loss, then regain. Testimony indicates that phenylpropanolamine hydrochloride effects may be limited to temporary weight loss that is quickly regained as fat, and so predisposes the user to further diet failure.

7. New research on obesity documents the deleterious effects of diet practices that waste lean muscle mass. Apparently, there simply exists no research on this possible undesirable effect as the primary mechanism of phenylpropanolamine hydrochloride weight loss, such as it may be.

Chairman Wyden stated that all witnesses expressed concern about the previously narrow focus of FDA's consideration of the efficacy and safety of phenylpropanolamine hydrochloride. He added that the Federal Trade Commission testified that population data showing wide misuse should weigh in any FDA decision on phenylpropanolamine's OTC status. Other scientific experts called for a wider consideration of efficacy than the narrow scope, short term clinical studies that constituted the prior focus of FDA scrutiny. One national society of physicians and several of the scientific witnesses called for removal of phenylpropanolamine hydrochloride from the OTC market entirely.

Subsequently, the agency received two submissions (Refs. 2 and 3) in rebuttal to the testimony given at the September 24, 1990 hearing and objecting to the data used to support testimony on phenylpropanolamine hydrochloride misuse in OTC weight control drug products.

In a letter sent to the agency on November 29, 1990 (Ref. 4), Congressman Wyden raised several additional issues for FDA consideration, as follows:

1. Does phenylpropanolamine hydrochloride cause or contribute to a rebound weight gain?

2. Does phenylpropanolamine hydrochloride cause muscle loss rather than loss of fat?

3. If phenylpropanolamine hydrochloride only works during the time it is taken, is life-long medication then required in order to maintain weight loss? If so, has this fact been considered in determining phenylpropanolamine hydrochloride's OTC classification?

4. Are phenylpropanolamine hydrochloride diet products generally used by consumers instead of exercise and behavioral change? Does phenylpropanolamine hydrochloride use in an unstructured and unsupervised setting actually decrease compliance with these essential components of successful weight loss?

Congressman Wyden also included with his letter a subcommittee staff report entitled "Phenylpropanolamine Diet Pills: Epidemiological Surveys, Adverse Drug Reactions, and Contacts with Poison Control Centers. A Comparison with Over-the-Counter Aspirin and Acetaminophen" (Ref. 5) and asked the agency to specifically address the following areas.

1. Any methodological problems with the assessment.

2. Any contradictory findings you may have on teen use and adult misuse.

3. Any contradictory findings you may have on the number of adverse incidents with phenylpropanolamine hydrochloride.

4. Any other population-based information about phenylpropanolamine hydrochloride's effect on weight loss.

In view of the new information related to phenylpropanolamine hydrochloride, the agency considers it necessary to resolve these issues regarding the safety, effectiveness, and possible misuse of phenylpropanolamine hydrochloride before publishing its tentative final monograph for OTC weight control drug products in the **Federal Register.** Therefore, the agency has concluded, under 21 CFR 10.65, that it would be in the public interest to hold an open public meeting to discuss the safety and effectiveness of phenylpropanolamine hydrochloride for OTC weight control use.

In order to provide a framework for the meeting, the agency believes that it will be useful to provide a discussion of the agency's review and evaluation on phenylpropanolamine hydrochloride prior to the information raised at the House Small Business Subcommittee on Regulation, Business Opportunities and Energy hearing held on September 24, 1990.

Safety

Studies measuring the effect on blood pressure of doses of phenylpropanolamine hydrochloride from 25 to 250 mg were submitted to the rulemaking for OTC weight control drug products (Refs. 6 and 7). The studies show that a single dose of phenylpropanolamine hydrochloride, which is an indirect-acting sympathomimetic amine, gives an early (lasts a few hours) dose-related pressor response and a later dose-related and position-related (principally in the erect position) depressor response. There appears to be tolerance to these effects such that additional doses have little or no pressor effect. It appears that phenylpropanolamine hydrochloride in doses below 50 mg immediate release and below 75 mg controlled (timed) release give pressor responses that would not be expected to be harmful. A 25 mg immediate release dose, for example, gives a mean pressor effect of 2 to 5 millimeters (mm) mercury (Refs. 8 and 9). Doses of the immediate release product above 50 mg immediate release give larger responses, and response to controlled release products above 75 mg are not well studied. An issue not resolvable by the available data is whether there are rare hyperresponsive patients, but such patients have not been identified.

Apart from effects on measured blood pressure, safety concerns regarding phenylpropanolamine hydrochloride

have arisen principally because of published reports of serious central nervous system adverse effects, especially stroke and intracranial hemorrhage. (See, e.g., Lake, et al. (Ref. 10) for a recent summary of published reports of adverse effects occurring following the use of phenylpropanolamine hydrochloride.) FDA has received similar reports as well. The presumed mechanism of these reported events, if indeed they are caused by phenylpropanolamine hydrochloride, is an exaggerated hypertensive response, although in most cases no large elevation was seen when the adverse effect was observed. Given the apparent rapid tolerance that develops to the hypertensive response to phenylpropanolamine hydrochloride (see discussion above), the adverse reaction reports that most plausibly represent an effect of phenylpropanolamine hydrochloride are those occurring after the first dose, or at least during the first day of phenylpropanolamine hydrochloride therapy, or after a pause in therapy and resumption of the drug. Only a few of the reported cases clearly meet this description (in others, precise time and dose information is not available). The relatively few first dose/first day cases, combined with the short duration and seemingly modest size of the phenylpropanolamine hydrochloride hypertensive response, tend to argue against phenylpropanolamine hydrochloride being the cause of these serious reactions. On the other hand, most reports of serious reactions involve single doses of at least 150 mg (two 75 mg controlled release dosage forms—not the recommended dose and presumably not the most commonly used dose—which could suggest a dose response relationship). Such a finding would make a causal relationship more plausible. The agency recognizes that it is possible, of course, that the excess of reports with higher doses could be a reporting artifact, the relatively large dose stimulating reporting of that event by making phenylpropanolamine hydrochloride cause seem more likely.

Although increased blood pressure after phenylpropanolamine hydrochloride use has generally been the major concern expressed, other mechanisms of an adverse central nervous system effect have also been suggested and these need to be considered, such as spasm/vasculitis (Refs. 11 and 12).

Affecting all of the safety considerations is the extreme difficulty of evaluating isolated reports, often missing critical data, of relatively rare events, especially in the OTC drug-use setting, where use information is extremely sparse and little is known about reporting practices. These are problems with evaluation of any spontaneous reports, but evaluation is even more difficult in the OTC drug-use setting. Without knowledge of use patterns and the ages of users, the agency has found it very difficult to determine whether the reported instances of central nervous system bleeding are excessive in relation to background rate. Nonetheless, if reasonable estimates of the background rate of spontaneous intracranial bleeds in relatively young women could be obtained, it might be possible to identify what seems like a marked excess of such events in persons who use phenylpropanolamine hydrochloride.

It should also be noted that, despite very wide use of phenylpropanolamine hydrochloride in cough-cold preparations at single doses of 25 mg and controlled release doses of 75 mg, very few instances of intracranial hemorrhage or stroke have been reported in this population. This could suggest that dose is indeed critical and that single doses of 25 mg immediate release and 75 mg controlled release are rarely exceeded by users of cough-cold products, or that less frequent reporting in this population (or excess reporting in the population using phenylpropanolamine hydrochloride weight control drug products) is a fundamental difference in the user populations.

In considering the extent and implications of possible misuse of phenylpropanolamine hydrochloride as an OTC weight control drug product, it is important that the term "misuse" be defined and differentiated from the term "abuse." In lay use, the word "abuse" is synonymous with "misuse." However, drugs with a potential for "abuse" are regulated under the Controlled Substances Act (21 U.S.C. 801 and 951), which is enforced by the Drug Enforcement Administration. Drugs that come under the jurisdiction of the Controlled Substances Act usually have the potential for causing psychic or physiological dependence. Phenylpropanolamine hydrochloride is currently not regulated under the Controlled Substances Act, and FDA is not aware of any specific information that it causes psychic or physiological dependence. On the other hand, misuse of a drug involves incorrect or unknowledgeable handling. Misuse of a drug would include overdosing, double dosing, or use in an inappropriate population, etc., but does not necessarily mean that the drug in question is a drug of abuse. In considering misuse of a drug with respect to its OTC availability, one must consider factors such as whether the drug has an adequate margin of safety under recommended conditions of use, whether the drug can be adequately labeled for its intended use, and whether its toxicity or other potentiality for harmful effect, or the method of its use, renders it not safe for use except under the supervision of a physician. As a general rule, misuse of a drug by a subset of the population has not been considered a sufficient reason for withholding such a drug from legitimate OTC uses by a majority of the population for whom the drug would be safe and effective, but this general rule could be reconsidered if miscuse were very dangerous or very widespread.

Effectiveness

The Panel reviewed a number of studies and concluded that phenylpropanolamine hydrochloride was effective as an OTC weight control drug product (47 FR 8466 at 8474 to 8476). The agency considers these studies as supportive but insufficient to establish this claim. However, more recently, the agency has reviewed two adequate and well-controlled studies that support the effectiveness of phenylpropanolamine hydrochloride (Refs. 13 and 14). The two studies are of similar design, i.e., randomized, double-blind, and placebo-controlled. The studies were conducted with patients who were 15 to 45 percent overweight. The main difference between the two trials was of duration; one (Ref. 13) was conducted over a 6-week period and the other (Ref. 14) over a 12-week period. All patients were placed on a 1,200 calorie diet and received 75 mg controlled release phenylpropanolamine hydrochloride capsules or palcebo at 10 a.m. each day. Both studies were positive in showing a statistically significantly greater weight loss in the phenylpropanolamine hydrochloride group. At the end of the 6-week study, the mean weight loss from baseline was 5.7 pounds for the phenylpropanolamine hydrochloride group and 2.4 pounds for the placebo group. In the 12-week study, the mean weight loss from baseline was 6.0 pounds for the phenylpropanolmine hydrochloride group and 2.4 pounds for the placebo group. Essentially all of the weight loss occurred by 8 weeks and was simply maintained for the remaining 4 weeks. The agency finds that these studies, together with some of the previously submitted data, support the effectiveness of phenylpropanolamine hydrochloride in a

75 mg controlled release dosage form when used in conjunction with an appropriate weight loss diet. A question that needs to be addressed is whether clinical studies in which subjects are periodically seen by a doctor, nurse, or health technician who provides dietary advice and scheduled follow-up (i.e., studies in a medically supervised setting) can document effectiveness in the OTC drug-use (i.e., no medical supervision) setting.

The agency is inviting interested individuals or groups to discuss the safety and effectiveness of phenylpropanolamine hydrochloride for OTC weight control use at an open meeting to be held on May 9, 1991. At that meeting, the agency will consider all of the issues raised in the above discussion. The following topics and questions are of particular importance:

I. Questions Relating to Safety

A. General

1. Are there clinical data that show that phenylpropanolamine hydrochloride at recommended OTC doses causes significant increases in blood pressure in some individuals?

2. Considering the above discussion of serious reported adverse events and other information, do data suggest a real, even if small, ability of phenylpropanolamine hydrochloride to induce major central nervous system adverse events at the recommended dose or at slightly excessive doses, or are the reports of such events not distinguishable from the spontaneous rate of these events?

3. Does the new epidemiological study (Ref. 5) contribute evidence that OTC phenylpropanolamine hydrochloride drug products represents a serious hazard to consumers, especially those under age 30?

4. Is there evidence that phenylpropanolamine hydrochloride diet pills have become a primary contributor to the deterioration of patients with anorexia nervosa?

B. Misuse

1. Is there evidence that a substantial fraction of purchasers of phenylpropanolamine hydrochloride products misuse the drug and do not follow the current label instructions or indications? What are the consequences of this misuse, if it occurs?

2. It has been claimed that phenylpropanolamine hydrochloride is misused by teenagers and young adults. What behavior would constitute misuse and what data are available to demonstrate that this use occurs and to document its adverse consequences? If misuse does occur and the adverse consequences are considered an important problem, would this be a basis for limiting the use of phenylpropanolamine hydrochloride to adults 18 years and over? How could this be done?

3. Are there adequate data demonstrating that some individuals, e.g., anorexics and bulimics, misuse phenylpropanolamine hydrochloride? If so, what are the documented consequences of this misuse?

II. Questions Relating to Efficacy

A. General

1. Anorectic agents, prescription or OTC, have been approved by FDA on the basis of evidence of short-term (6–12 week) weight loss. While long-term effects are pertinent, the agency believes that the question of long-term use is relevant to both prescription and OTC anorectic agents and should be taken up in a different context. Considering just the short-term results, does the fact that the studies were carried out in a medical setting decrease their usefulness as support for an OTC (no medical supervision) use?

2. Are there any data to suggest that phenylpropanolamine hydrochloride causes a loss of lean muscle mass rather than a loss of fat? If there are no pertinent study data, is it plausible that it would do so?

3. Are there data indicating that phenylpropanolamine hydrochloride causes or contributes to rebound weight gain? New research on obesity suggests that some diet practices, especially those leading to rapid weight loss, are associated with rebound weight gain. Testimony presented at the September 24, 1990 hearing contended that phenylpropanolamine hydrochloride effects may be limited to temporary weight loss that is quickly regained as fat, and so predisposes the user to further diet failure. Can phenylpropanolamine hydrochloride related weight loss be distinguished from other weight loss in this respect?

B. Labeling

1. There are no data to indicate that phenylpropanolamine hydrochloride at doses higher than 75 mg per day are more effective than the 75 mg dose, yet these doses have been used. How best can weight control drug products be labeled to convey to consumers that effectiveness is not increased with an increase in dose?

2. Assuming that phenylpropanolamine hydrochloride remains OTC for weight control use, in addition to the labeling proposed by the Panel, what specific labeling should be recommended?

In this document, the agency is asking for comment and any new data on these and other issues specifically related to the safety and effectiveness of phenylpropanolamine hydrochloride for OTC weight control use. Any comments, new data, and presentations at the public meeting should be organized in such a manner to address specifically these issues. Data previously submitted to the rulemaking for OTC weight control drug products need not be resubmitted.

The safety of phenylpropanolamine hydrochloride for nasal decongestant use is not specifically at issue during the public meeting. However, if evidence becomes available indicating that there may be safety problems connected with the use of phenylpropanolamine hydrochloride in cough-cold nasal decongestant drug products, appropriate action(s) will be taken.

The agency requests information on the above questions from any interested person. Any individual or group wishing to submit data relevant to the questions above prior to the public meeting should send them on or before May 1, 1991, to Docket No. 81N–0022, Dockets Management Branch (address above). Any individual or group wishing to make a presentation at the public meeting should contact Helen Cothran or Mary Robinson, Division of OTC Drug Evaluation (HFD–210), Office of Drug Standards, Center for Drug Evaluation and Research, 5600 Fishers Lane, Rockville, MD 20857, 301–295–8006. Interested persons who wish to participate must also send a notice of participation on or before May 1, 1991, to the Dockets Management Branch (address above). All notices submitted should be identified with the docket number found in brackets in the heading of this document and should contain the following information: Name; address; telephone number; business affiliation, if any, of the person desiring to make a presentation; and the subject and approximate amount of time requested for the presentation.

Groups having similar interests are requested to consolidate their comments and present them through a single representative. FDA may require joint presentations by persons with common interests. After reviewing the notices of participation, FDA will notify each participant of the schedule and time allotted to each person.

The administrative record for the rulemaking for OTC weight control drug products is being reopened to specifically include all data submitted

since the record previously closed on July 26, 1982 and the proceedings of this public meeting. The administrative record will remain open until August 7, 1991 to allow comments on matters raised at the public meeting. Thereafter, the administrative record will remain closed until the agency publishes its proposed regulation for OTC weight control drug products.

References

(1) Letter from The Honorable Ron Wyden, United States House of Representatives Committee on Small Business, to James S. Benson, FDA., comment No. LET60, Docket No. 81N-0022, Dockets Management Branch.

(2) Comment No. C32, Docket No. 81N-0022, Dockets Management Branch.

(3) Comment No. CP13, Docket No. 81N-0022, Dockets Management Branch.

(4) Letter from The Honorable Ron Wyden, United States House of Representatives Committee on Small Business, to James S. Benson, FDA, Comment No. C45, Docket No. 81N-0022, Dockets Management Branch.

(5) Raford, P., "Phenylpropanolamine Diet Pills: Epidemiological Surveys, Adverse Drug Reaction, and Contacts with Poison Control Centers. A Comparison with Over-the-Counter Aspirin and Acetaminophen," unpublished paper, dated September 24, 1990, in Comment No. C45, Docket No. 81N-0022, Dockets Management Branch.

(6) Comments No. RPT9 and RPT11, Docket No. 81N-0022, Dockets Management Branch.

(7) Comments No. RPT4 and RPT6, Docket No. 76N-052N, Dockets Management Branch.

(8) Dowse, R., S.S. Scherzinger, and I. Kanfer, "Serum Concentrations of Phenylpropanolamine and Associated Effects on Blood Pressure in Normotensive Subjects: a Pilot Study," "International Journal of Clinical Pharmacology, Therapy and Toxicology" 28:205-210, 1990.

(9) Blackburn, G.L., et al., "Determinants of the Pressor Effect of Phenylpropanolamine in Healthy Subjects," "Journal of the American Medical Association" 261:3267-3272, 1989.

(10) Lake, C.R., et. al., "Adverse Drug Effects Attributed to Phenylpropanolamine: A Review of 142 Case Reports," "The American Journal of Medicine," 89:195-208, 1990.

(11) Forman, H.P., et. al., "Cerebral Vasculitis and Hemorrhage in an Adolescent Taking Diet Pills Containing Phenylpropanolamine: Case Report and Review of Literature," "Pediatrics," 83:737-741, 1989.

(12) Fallis, R.J., "Cerebral Vasculitis and Hemorrhage Associated With Phenylpropanolamine," "Neurology," 35:405-407, 1985.

(13) Protocol 85-004, Comment No. CP11, Docket No. 81N-0022, Dockets Management Branch.

(14) Protocol 87-010, Comment No. CP11, Docket No. 81N-0022, Dockets Management Branch.

Dated: March 24, 1991.

David A. Kessler,

Commissioner of Food and Drugs.

[FR Doc. 91-7517 Filed 3-29-91; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF LABOR

Office of the Secretary

29 CFR Part 92

RIN 1214-AA04

Redwood Employee Protection Program

AGENCY: Department of Labor.

ACTION: Notice of proposed rulemaking; request for comments.

SUMMARY: The Department of Labor is responsible for administering significant aspects of the Redwood Employee Protection Program established by title II of the Redwood National Park Expansion Act of 1978 (Pub. L. 95-250). The statute provides benefits to eligible employees to timber harvesting and related wood processing firms adversely affected by the Park expansion. September 30, 1989 was the final date for industry workers to establish basic eligibility and it is our intent now to announce a date certain after which time any additional applications for benefits, or appeals of previous benefit decisions, will be considered untimely. The intended effect of this action is to bring to a close this Agency's responsibility under this statute. If there is any reason you believe this rule should not be adopted, the Department requests your comments.

DATES: Comments are due on or before May 1, 1990.

ADDRESSES: Submit written comments to Kelley Andrews, Director, Office of Statutory Programs, U.S. Department of Labor, room S-2203, 200 Constitution Avenue NW., Washington, DC 20210.

FOR FURTHER INFORMATION CONTACT: Kelley Andrews of the Department of Labor at Fax: (202) 523-8762 or Telephone: (202) 357-0473. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: Title II of the Redwood National Park Expansion Act of 1978 provides monetary and non-monetary benefits to eligible employees of timber harvesting and related wood processing firms adversely affected (laid off, terminated or downgraded) by the Park expansion. Under the Act, employees were required to apply for benefits no later than September 30, 1980. Some older employees were eligible for benefits until age 65—about September 30,1989.

Determination Appeals

In accordance with title II of the Act, employees whose applications for benefits were rejected had the right to appeal to this agency for review and reconsideration prior to October 1, 1989. While new appeals have ceased, this regulation provides official notice of the expiration of the appeal process and completes this agency's determination review responsibility for benefit eligibility. Therefore, any appeal submitted to this agency for review and reconsideration after the adoption of this regulation will be considered untimely and dismissed. Any such appeal resulting from actions taken on any cases currently before the Secretary will, however, be considered timely.

Health Benefit Claims

Under title II of the Act, this agency has been reviewing health benefits claims for eligible employees and ensuring their payment. While no new health claims could be incurred after September 30, 1989, this agency has allowed a grace period for eligible employees to gather cost statements from health-care providers to submit to this agency. This regulation provides official notice of the expiration of the period allotted for the submission of health benefits claims. Therefore, claims submitted after the adoption of this regulation will be considered untimely and will be returned.

Pension Benefit Claims

Also under title II of the Act, this agency has been reviewing pension benefit claims for eligible employees. September 30, 1989 was the final date for pension eligibility. This regulation provides official notice of the expiration of the period allotted for the submission of pension claims. Therefore, claims submitted after the adoption of this regulation will be considered untimely.

E.O. 12291

This rule does not have the financial or other impact to make it a major rule and, therefore, the preparation of a regulatory impact analysis is not necessary under E.O. 12291.

Paperwork Reduction Act

There are no information collection requirements under this rule.

Regulatory Flexibility Act

This rule will not have a significant economic impact upon a substantial number of small entitles. The Secretary has certified this fact to the Small Business Administration, and no regulatory impact analysis is necessary under the Regulatory Flexibility Act.

List of Subjects in 29 CFR Part 92.

Unemployment compensation, National parks. Accordingly, it is

proposed that 29 CFR part 92 be removed.

Dated at Washington, DC, this 25th day of March 1991.

H. Charles Spring,

Acting Deputy Under Secretary.

[FR Doc. 91-7483 Filed 3-29-91; 8:45 am]

BILLING CODE 4510-85-M

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 913

Illinois Permanent Regulatory Program; Permit Issuance

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Proposed rule.

SUMMARY: OSM is announcing the receipt of a proposed amendment to the Illinois permanent regulatory program (hereinafter referred to as the Illinois program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The amendment was initiated by the Illinois Department of Mines and Minerals (Department) to respond to recent changes in the Illinois Surface Coal Mining Land Conservation and Reclamation Act (State Act) and to make the requirements of the Illinois program no less effective than the Federal program. It concerns changes made to the Illinois Administrative Code (IAC), title 62, Mining chapter I.

This notice sets forth the times and locations that the Illinois program and proposed amendment to that program are available for public inspection, the comment period during which interested persons may submit written comments on the proposed amendment and the procedures that will be followed regarding the public hearing, if one is requested.

DATES: Written comments must be received on or before 4:00 p.m. on May 1, 1991. If requested, a public hearing on the proposed amendment will be held at 1 p.m. on April 26, 1991. Requests to present oral testimony at the hearing must be received on or before 4 p.m. on April 16, 1991.

ADDRESSES: Written comments should be mailed or hand delivered to: Mr. James F. Fulton, Director, Springfield Field Office, at the address listed below. Copies of the Illinois program, the proposed amendment, and all written comments received in response to this notice will be available for public review at the address listed below during normal business hours, Monday through Friday, excluding holidays. Each requester may receive, free of charge, one copy of the proposed amendment by contacting OSM's Springfield Field Office.

Office of Surface Mining Reclamation and Enforcement, Springfield Field Office, 511 West Capitol, suite 202, Springfield, Illinois 62704, Telephone: (217) 492-4495.

Illinois Department of Mines and Minerals, 300 West Jefferson Street, suite 300, Springfield, Illinois 62791, Telephone (217) 782-4970.

FOR FURTHER INFORMATION CONTACT: James F. Fulton, Director, Springfield Field Office; (217) 492-4495.

SUPPLEMENTARY INFORMATION:

I. Background

On June 1, 1982, the Secretary of the Interior conditionally approved the Illinois program. Information pertinent to the general background of the Illinois program submission, as well as the Secretary's findings, the disposition of comments, and a detailed explanation of the conditions of approval can be found in the June 1, 1982, **Federal Register** (47 FR 23883). Subsequent actions concerning the conditions of approval and program amendments are identified at 30 CFR 913.11, 913.15, 913.16 and 913.17.

II. Discussion of Proposed Amendment

On August 29, 1990, the Illinois General Assembly amended section 2.11(d) of the State act in order to make the issuance of coal mine permits in Illinois consistent with the counterpart provisions of section 541(c) of SMCRA. This amendment of the State Act requires that the Illinois program also be amended. Therefore, in response to the statutory change and in order to make the requirements of the Illinois progam no less effective than the Federal program, the Department by letter dated March 5, 1991 (Administrative Record No. IL-1144), submitted proposed changes to the State regulation at 62 IAC 1773.19, which sets forth its requirements for permit issuance. The proposed changes include the addition of the world "and" in subsection (b)(1); the deletion of subsection (b)(2), which required a 30-day waiting period for permit issuance after mailing written notification of the Department's final permit decision as provided in 62 IAC 1773.19(a); and the renumbering of subsection (b)(3) to (b)(2). The regulation now reads: "b) The permit shall be deemed to be issued when: (1) The permit application, as originally submitted or as modified, is approved by the Department; and (2) Permit fees and reclamation bond, in the form and amounts set by 62 Ill. Adm. Code 1777.17 and 1800, have been received and accepted by the Department."

III. Public Comments Procedures

In accordance with the provisions of 30 CFR 732.17(h), OSM is seeking comments on whether the proposed amendment satisfies the applicable program approval criteria of 30 CFR 732.15.

If the amendment is deemed adequate, it will become part of the Illinois program.

Written Comments

Written comments should be specific, pertain only to the issues proposed in this rulemaking, and include explanations in support of the commenter's recommendations. Comments received after the time indicated under "DATES" or at locations other than the OSM Springfield Field Office will not necessarily be considered and included in the Administrative Record for the final rulemaking.

Public Hearing

Persons wishing to comment at the public hearing should contact the person listed under "FOR FURTHER INFORMATION CONTACT" by 4 p.m. on April 16, 1991. If no one requests an opportunity to comment at a public hearing, the hearing will not be held.

Filing of a written statement at the time of the hearing is requested as it will greatly assist the transcriber. Submission of written statements in advance of the hearing will allow OSM officials to prepare adequate responses and appropriate questions.

The public hearing will continue on the specified date until all persons scheduled to comment have been heard. Persons in the audience who have not been scheduled to comment, and who wish to do so, will be heard following those scheduled. The hearing will end after all persons scheduled to comment and persons present in the audience who wish to comment have been heard.

Public Meeting

If only one persons requests an opportunity to comment at a hearing, a public meeting rather than a public hearing, may be held. Persons wishing to meet with OSM representatives to discuss the proposed amendment may request a meeting at the OSM office listed under "ADDRESSES" by contacting the persons listed under "FOR FURTHER INFORMATION