(2) All biological products in USDA-licensed establishments, whether licensed by USDA or by the State, shall be prepared only in locations indicated in legends filed in accordance with 9 CFR part 108. A description of each State-licensed product must be filed with the Animal and Plant Health Inspection Service as part of the blueprint legends and must be sufficient for Animal and Plant Health Inspection Service to determine any risk to the production of other products in the licensed establishment and to determine that adequate procedures are followed to prevent contamination during production.

(3) Records in such establishments must be maintained in accordance with §§ 116.1 and 116.2 of this subchapter and shall include all products licensed by the State or USDA.

(4) Reports prescribed in § 116.5 of this subchapter for USDA-licensed establishments shall be submitted for all veterinary biological products in the establishment.

(5) Under the following conditions, an autogenous biologic may be produced in a USDA-licensed establishment under either a State or U.S. Veterinary Biological Product License:

(i) When a culture of microorganisms, isolated from a herd in a State, is received at a USDA-licensed establishment that is in the same State but that holds both a State and a U.S. Veterinary Biological Products License for autogenous biologics, the isolate shall be designated by the licensee for use in the production of an autogenous biological product under either the State product license, or the U.S. Veterinary Biological Product License: *Provided*, That the isolate meets the requirements of the respective regulatory authority for an autogenous biologic. If, after producing the product pursuant to one license, the licensee elects to produce an autogenous biologic from the same isolate under provisions of the other license, the licensee may do so only with the approval of the other licensing authority.

(ii) The true name of a State-licensed autogenous biologic shall specify the State of licensure: e.g. ''(State) Autogenous Bacterin'' or ''(State) Autogenous Vaccine''.

Done in Washington, DC, this 28th day of February 1995.

Terry L. Medley,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 95–5407 Filed 3–3–95; 8:45 am]

BILLING CODE 3410–34–M

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1700

Requirements for the Special Packaging of Household Substances; Opportunity for Oral Comment

AGENCY: Consumer Product Safety Commission.

ACTION: Opportunity for presentation of oral public comments.

SUMMARY: The Commission announces an opportunity for the presentation of oral comments on two issues that were recently raised concerning amendments the Commission is considering to its regulations under the Poison Prevention Packaging Act of 1970 (PPPA) for child-resistant packaging to change the child and adult tests under which child-resistant packaging is evaluated.

Immediately after issuing a rule amending the PPPA test protocol, the Commission was provided with comments on the final rule that had not previously been submitted to the agency during the course of the rulemaking. As a result, the Commission, on February 9, 1995, voted to withhold publication of the final rule in order to consider these new arguments.

The new arguments can be summarized as follows. First, in establishing an adult test panel consisting of adults aged 60–75, the Commission allegedly exceeded its statutory authority to require that child-resistant packaging not be difficult for ''normal adults'' to use properly. Second, the rule allegedly addresses consumer convenience, rather than safety, which the comment claims is not properly the subject of a Commission regulation.

The Commission has provided that written comments, limited to these two issues, may be submitted until March 7, 1995. In addition, the Commission is providing the opportunity for interested parties to present oral comments, on these two issues alone, limited to a maximum of 10 minutes per commenter.

DATES: Oral comments limited to the new issues described below may be presented to the Commission at a Commission hearing beginning at 10:00 a.m., March 16, 1995. A request to present oral comments and an outline or text of the comments must be received by the Commission on or before March 10, 1995.

ADDRESSES: The hearing will be held in the Commission's Hearing Room, 4330 East-West Highway, 4th Floor, Bethesda, MD 20814. Requests to present comments and outlines or text of the comments should be mailed to the Office of the Secretary, Consumer Product Safety Commission, Washington, DC 20207, or delivered to the Office of the Secretary, Consumer Product Safety Commission, Room 501, 4340 East-West Highway, Bethesda, MD 20814.

FOR FURTHER INFORMATION CONTACT: Suzanne Barone, Ph.D., Project Manager, Consumer Product Safety Commission, Washington, DC 20207; telephone (301) 504–0477, ext. 1196.

SUPPLEMENTARY INFORMATION: The Poison Prevention Packaging Act of 1970 (''PPPA''), 15 U.S.C. 1471–1476, authorizes the Consumer Product Safety Commission to issue requirements that certain household substances be sold in child-resistant (''CR'') packaging. Under the PPPA, the Commission has defined and established standards for such ''special'' packaging. 16 CFR 1700.1(b)(4), 1700.3, 1700.15, and 1700.20. The Commission has also determined which household substances are required to have the special packaging. 16 CFR 1700.14.

Congress provided that to comply with the special packaging requirements, a package must resist entry by most young children and must be ''not difficult'' for ''normal adults'' to open and properly resecure, within specified time periods. 15 U.S.C. 1471(4). The Commission's existing regulations were developed before the widespread use of CR packaging (''CRP'') and, therefore, without the benefit of the actual use experience and test data that since have become available.

The current adult test protocol, 16 CFR 1700.20(a) (4) and (5), specifies a test panel of 100 adults, ages 18 through 45 years. Seventy percent of the adults must be females and 30 percent must be males. The test period is 5 minutes. The adults are given the test package and asked to open and then properly close the package. For a package to meet the PPPA effectiveness criteria, at least 90 percent of the adults must be able to open and, if appropriate, properly close the package within the 5-minute test period. 16 CFR 1700.15(b)(2).

Although the PPPA has significantly reduced the number of poisonings of young children, deaths and injuries resulting from these accidental ingestions continue to be a substantial problem. For example, in 1993 alone, approximately 140,000 children under 5 years old were treated in hospital emergency rooms for suspected or actual poisonings. Also in 1993, poison control centers received reports of more

than 6,000 poisonings of young children with ''moderate'' or ''major'' (life-threatening) effects. In addition, 42 children died in these accidents in 1992, the last year for which the Commission has complete data.

During the more than 20 years since the PPPA was adopted, the Commission has found that, contrary to requirements of the PPPA, ''normal'' adults of all ages have difficulty using typical CRP. Moreover, the Commission's data indicate that the difficulty in using CRP results in a substantial number of accidental ingestions by young children because adults purchase hazardous substances in non-CRP or disable CRP by leaving the caps off or loose or transferring the package contents to another container.

Accordingly, the Commission sought to address the safety hazard created by difficult to open CRP. On January 19, 1983, the Commission published an advance notice of proposed rulemaking (''ANPR'') outlining its concerns in this area and explaining and seeking comment on possible actions to increase the proper use of CRP, to simplify the test procedures, and to make the test procedures less affected by possible variables. 48 FR 2389.

Older adults typically have the most difficulty with CRP. Therefore, in order to eliminate the currently-marketed CR package designs that are most difficult for ''normal adults'' of all ages to open, the Commission indicated that older adults, ages from 60–75 years, could be substituted for the current panel of 100 18–45-year-olds.

After considering comments on the ANPR and other available information, the Commission proposed amendments to the protocol to address this problem. The proposed amendments would also change the protocol to make the test results more consistent and make the child test easier to perform. The Commission published its initial proposal in the **Federal Register** of October 5, 1990, for public comment. 55 FR 40856.

In addition to the requests for comments in January 1983 and October 1990 noted above, the Commission announced additional comment periods on March 5, 1991, (56 FR 9181) and March 21, 1994 (59 FR 13264). The Commission's staff evaluated the comments received in response to each of these requests.

On December 20, 1994, the Commission was briefed by its staff on the comments on the proposed rule and the changes recommended by the staff. On January 6, 1995, the Commission met and decided to approve the rule recommended by the staff, but to exclude from the scope of the rule those products that must be packaged in metal cans or aerosol form. The staff made appropriate changes to the draft **Federal Register** notice that would issue the final rule, and that notice was approved by the Commission on February 6, 1995.

Immediately thereafter, the Coalition for Responsible Packaging, an industry group, raised concerns about the Commission's action. Most of these concerns already had been addressed in the rulemaking proceeding. Two concerns, however, had not been the subject of specific comments by interested parties in this rulemaking.

Specifically, the new comments can be summarized as follows. First, in establishing an adult test panel consisting of adults aged 60–75, the Commission allegedly exceeded its statutory authority to require that child-resistant packaging not be difficult for ''normal adults'' to use properly. Second, the rule allegedly addresses consumer convenience, rather than safety, which the comment claims is not properly the subject of a Commission regulation. In addition, the second comment contends that to the extent that child-resistant packages exist that will pass the ''senior friendly'' test approved by the Commission, market forces will be an adequate and more appropriate mechanism to ensure that the more convenient packaging will be adopted.

The Commission wanted to assure that it had an opportunity to consider these new arguments that had not previously been raised in the rulemaking. Accordingly, on February 8, 1995, the Commission voted unanimously to withhold publication of the **Federal Register** notice that would have issued the final rule, to consider the new arguments.

On February 21, 1995, the Commission published a **Federal Register** notice announcing that written comments, limited to these two issues only, could be submitted until March 7, 1995. 60 FR 9654. The Commission has now decided to also receive oral comments on these two new issues. Oral comments on these new issues alone may be presented to the Commission at a Commission hearing beginning at 10:00 a.m., March 16, 1995.

A request to present oral comments and an outline or text of the comments must be received by the Commission on or before March 10, 1995. The oral comments shall be limited to 10 minutes per commenter. The Commission reserves the right to further limit repetitious comments. Comments addressing other issues will not be considered.

The hearing will be held in the Commission's Hearing Room, 4330 East-West Highway, 4th Floor, Bethesda, MD 20814. Requests to present oral comments and outlines or text of the comments shall be mailed to the Office of the Secretary, Consumer Product Safety Commission, Washington, D.C. 20207, or delivered to the Office of the Secretary, Consumer Product Safety Commission, Room 501, 4340 East-West Highway, Bethesda, MD 20814.

Dated: March 1, 1995.

Sadye E. Dunn,

Secretary, Consumer Product Safety Commission.

[FR Doc. 95–5502 Filed 3–2–95; 11:42 am]

BILLING CODE 6355–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Social Security Administration

20 CFR Parts 404 and 416

[Regs. No. 4 and 16]

RIN 0960–AB73

Determining Disability and Blindness; Substantial Gainful Activity Guides

AGENCY: Social Security Administration, HHS.

ACTION: Proposed rules.

SUMMARY: These proposed rules reflect amendments to the Social Security Act (the Act) concerning the trial work period and the disability insurance reentitlement period. The proposed rules also clarify certain standards we use to determine whether work is substantial gainful activity and whether an individual is entitled to a trial work period, thereby further explaining how we determine disability under titles II and XVI of the Act.

DATES: To be sure that your comments are considered, we must receive them no later than May 5, 1995.

ADDRESSES: Comments should be telefaxed to (410) 966–0869 or submitted in writing to the Commissioner of Social Security, Department of Health and Human Services, P.O. Box 1585, Baltimore, MD 21235, or delivered to the Office of Regulations, Social Security Administration, 3–B–1 Operations Building, 6401 Security Boulevard, Baltimore, MD 21235, between 8 a.m. and 4:30 p.m. on regular business days. Comments may be inspected during these same hours by making arrangements with the contact person shown below.