

whether you are disabled under § 416.920(f)(1), we will consider your chronological age in combination with your residual functional capacity, education, and work experience; we will not consider your ability to adjust to other work on the basis of your age alone. In determining the extent to which age affects a person's ability to adjust to other work, we consider advancing age to be an increasingly limiting factor in the person's ability to make such an adjustment, as we explain in paragraphs (c) through (e) of this section. If you are unemployed because of your age, but you still have the ability to do substantial gainful activity, we will find that you are not disabled. In paragraphs (b) through (e) of this section and in appendix 2 of subpart P of part 404 of this chapter, we explain in more detail how we consider your age as a vocational factor.

(b) *How we apply the age categories.* When we make a finding about your ability to do other work under § 416.920(f)(1), we will use the age categories in paragraphs (c) through (e) of this section. We will use each of the age categories that applies to you during the period for which we must determine if you are disabled. We will not apply the age categories mechanically in a borderline situation. If you are within a few days to a few months of reaching an older age category, and using the older age category could result in a determination or decision that you are disabled, we will consider whether to use the older age category after evaluation of the overall impact of all of your vocational factors.

(c) *Younger person.* If you are a younger person (under age 50), we generally do not consider that your age will seriously affect your ability to adjust to other work. However, in some circumstances, we consider that persons age 45–49 are more limited in their ability to adjust to other work than persons who have not attained age 45. See Rule 201.17 in appendix 2 of subpart P of part 404 of this chapter.

(d) *Person closely approaching advanced age.* If you are closely approaching advanced age (age 50–54), we will consider that your age along with a severe impairment(s) and limited work experience may seriously affect your ability to adjust to other work.

(e) *Person of advanced age.* We consider that at advanced age (age 55 or older) chronological age significantly affects a person's ability to adjust to other work. We have special rules for persons of advanced age and for persons in this category who are closely

approaching retirement age (age 60–64). See § 16.968(d)(4).

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6. Section 416.96 is amended by adding a new paragraph (d)(4) to read as follows:

§ 416.968 Skill requirements.

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(d) *Skills that can be used in other work (transferability)* * * *.

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(4) *Transferability of skills for individuals of advanced age.* If you are of advanced age (age 55 or older), and you have a severe impairment(s) that limits you to sedentary or light work, we will find that you cannot make an adjustment to other work unless you have skills that you can use in (transfer to) other skilled or semiskilled work that you can do despite your impairment(s). We will decide if you have transferable skills as follows. If you are of advanced age and you have a severe impairment(s) that limits you to no more than sedentary work, we will find that you have skills that are transferable to skilled or semiskilled sedentary work only if the sedentary work is so similar to your previous work that you would need to make very little, if any, vocational adjustment in terms of tools, work processes, work settings, or the industry. (See § 416.967(a) and § 201.00(f) of appendix 2 of subpart P of part 404 of this chapter.) If you are of advanced age but have not attained age 60, and you have a severe impairment(s) that limits you to not more than *light* work, we will apply the rules in paragraphs (d)(1) through (d)(3) of this section to decide if you have skills that are transferable to skilled or semiskilled light work (see § 416.967(b)). If you are closely approaching retirement age (age 60–64) and you have a severe impairment(s) that limits you to no more than *light* work, we will find that you have skills that are transferable to skilled or semiskilled light work only if the light work is so similar to your previous work that you would need to make very little, if any, vocational adjustment in terms of tools, work processes, work settings, or the industry. (See § 416.967(b) and § 202.00(f) of appendix 2 of subpart P of part 404 of this chapter.)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 98P–0683]

Food Labeling: Health Claims; Soy Protein and Coronary Heart Disease

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; notice of extension of period for issuance of final rule.

SUMMARY: The Food and Drug Administration (FDA) is extending, for 80 days, the period for issuance of a final rule in response to its proposal of November 10, 1998, entitled 'Food Labeling: Health Claims; Soy Protein and Coronary Heart Disease.' FDA's regulations require the agency to issue a notice of such extension if it finds, for cause, that it is unable to issue a final rule within 270 days from the November 10, 1998, date of publication of the proposal. Comments to that proposal have persuaded the agency of the need to propose an alternative procedure to assess compliance with qualifying amounts of soy protein in foods that may bear the proposed health claim. FDA will publish a rep proposal of the procedure for compliance assessment in the **Federal Register** shortly. The agency then intends to issue one final rule in response to both proposals on or before October 25, 1999.

FOR FURTHER INFORMATION CONTACT: Susan M. Pilch, Center for Food Safety and Applied Nutrition (HFS–465), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4500.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 22, 1997 (62 FR 28229), FDA published a final rule to amend § 101.70 (21 CFR 101.70) of its regulations to provide a timeframe in which it will issue, in rulemakings on health claims, final rules announcing whether it will authorize the use of the claim at issue and to provide for extensions of that timeframe for cause. In that final rule, FDA adopted § 101.70(j)(4)(i), which provides that within 270 days of the date of publication of a proposal to authorize a health claim, the agency will publish a final rule that either authorizes the use of a health claim or explains why the agency has decided not to authorize one. FDA also adopted § 101.70(j)(4)(ii), which provides that, for cause, the agency may extend, no more than twice, the period in which it will publish a final rule and that each such extension

will be for no more than 90 days. This regulation further requires that FDA publish a notice of any such extension in the **Federal Register**, and that it explain in that notice the basis for the extension, the length of the extension, and the date by which the final rule will be published (§ 101.70(j)(4)(ii)).

In the **Federal Register** of May 14, 1998 (63 FR 26717), FDA published a final rule in part to amend § 101.70 in response to section 302 of the Food and Drug Administration Modernization Act of 1997 (FDAMA). Section 302 of FDAMA amended section 403(r)(4)(A)(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(r)(4)(A)(i)) to provide, in part, that FDA must publish a final rule on a health claim petition within 540 days of receipt of the petition or FDA is required to provide the relevant House and Senate legislative committees with the reason for failing to do so. Accordingly, FDA amended § 101.70(j)(4)(ii) to state that rulemakings on health claim petitions shall be completed within 540 days of receipt of those petitions. FDA noted that, depending upon how much time the agency uses to file a petition and publish a proposed rule in response to it, the agency may be limited to only one extension under § 101.70(j)(4)(ii), and the extension may be limited to fewer than 90 days (63 FR 26717 at 26718).

In the **Federal Register** of November 10, 1998 (63 FR 62977), FDA proposed adding § 101.82 to authorize the use, on food labels and in food labeling, of health claims on the association between soy protein and reduced risk of coronary heart disease (CHD) (the soy protein proposed rule). In the soy protein proposed rule, the agency presented the rationale for a health claim on this food-disease relationship as provided for under the standard in section 403(r)(3)(B)(i) of the act and 21 CFR 101.14(c) of FDA's regulations. The agency tentatively concluded that, based on the totality of publicly available scientific evidence, soy protein included in a diet low in saturated fat and cholesterol may reduce the risk of CHD. The soy protein proposed rule included qualifying criteria for the purpose of identifying soy protein-containing foods eligible to bear the proposed health claim and a proposed analytical method for assessing compliance with the qualifying criteria. Comments received in response to the soy protein proposed rule have persuaded FDA that the proposed method for assessment of compliance is inadequate for many products. Accordingly, FDA intends to publish, in a separate document, a reproposal for an

alternative procedure. This procedure would rely on measurement of total protein and require manufacturers, in certain circumstances, to maintain records that document the amount of soy protein in products and to make these records available to appropriate regulatory officials for inspection and copying upon request.

To publish a final rule regarding a health claim for soy protein and CHD within 270 days of the date of publication of the proposed rule, which was November 10, 1998, the agency should publish the final rule on or before August 6, 1999. However, because of the need to provide for public notice and comment on the reproposal, FDA hereby gives notice that there is cause to extend the period for publication of the final rule for a period of 80 days. FDA will, thus, publish a single final rule in response to both proposals on or before October 25, 1999, which is within 540 days of the date of receipt of the petition.

Dated: July 28, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning and Legislation.

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LIBRARY OF CONGRESS

Copyright Office

37 CFR Part 201

[Docket No. RM 99-5]

Notice and Recordkeeping for Subscription Digital Transmissions

AGENCY: Copyright Office, Library of Congress.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Copyright Office of the Library of Congress is proposing to amend the regulation that requires the filing of an initial notice of digital transmissions of sound recordings under statutory license with the Copyright Office to adjust for changes brought about by the passage of the Digital Millennium Copyright Act of 1998.

DATES: Comments are due September 3, 1999.

ADDRESSES: An original and ten copies of the comments shall be delivered to: Office of General Counsel, Copyright Office, LM-403, James Madison Memorial Building, 101 Independence Avenue, S.E., Washington, D.C. 20559-6000, or mailed to: David O. Carson, General Counsel, Copyright GC/I&R,

P.O. Box 70400, Southwest Station, Washington, D.C. 20024.

FOR FURTHER INFORMATION CONTACT:

David O. Carson, General Counsel, or Tanya M. Sandros, Attorney Advisor, Copyright GC/I&R, P.O. Box 70400, Southwest Station, Washington, D.C. 20024. Telephone: (202) 707-8380. Telefax: (202) 707-8366.

SUPPLEMENTARY INFORMATION:

Background

On November 1, 1995, Congress enacted the Digital Performance Act in Sound Recordings Act of 1995 ("DPRA"), Public Law 104-39, 109 Stat. 336 (1995). The DPRA gave to sound recording copyright owners an exclusive right to perform their works publicly by means of a digital audio transmission. 17 U.S.C. 106(6). The new right, however, was subject to certain limitations, including exemptions for certain digital transmissions, 17 U.S.C. 114(d)(1), and the creation of a statutory license for nonexempt digital subscription services. 17 U.S.C. 114(d)(2).

The statutory license requires adherence to regulations under which copyright owners may receive reasonable notice of use of their sound recordings under the statutory license, and under which entities performing the sound recordings shall keep and make available records of such use. 17 U.S.C. 114(f)(2). On May 13, 1996, the Copyright Office initiated a rulemaking proceeding to promulgate regulations to govern the notice and recordkeeping requirements. 61 FR 22004 (May 13, 1996). This rulemaking concluded with the issuance of interim rules to govern the filing of an initial notice of digital transmissions of sound recordings under statutory license, 37 CFR 201.35, and the filing of reports of use of sound recordings under statutory license, 37 CFR 201.36. See 63 FR 34289 (June 24, 1998).

At the time these regulations were announced, only three noninteractive, nonsubscription, digital transmissions services (DMX, Inc., Digital Cable Radio Associates/Music Choice, and Muzak, Inc.) were in operation and considered eligible for the license. Consequently, the Office prescribed a period for filing initial notices such that all existing services, which were already operating in accordance with the section 114 license, had to submit their notices within 45 days of the effective date of the regulation. Section 201.35(f) reads, in part, as follows: "A Service shall file the Initial Notice with the Licensing Division of the Copyright Office prior to the first transmission of sound