§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

Saab Aircraft AB: Docket 97–NM–126–AD.

Applicability: Model SAAB 2000 series airplanes having serial numbers –002 through –043 inclusive, certificated in any category.

N**ote 1:** This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (b) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent discrepancies of the check valve, which could result in improper functioning of the engine fire extinguishing system, accomplish the following:

(a) Within 2 months after the effective date of this AD, perform an inspection of the two-way check valve on the engine fire extinguishing system for discrepancies, in accordance with Saab Service Bulletin 2000–26–010, dated July 5, 1996. If any discrepancy is found, prior to further flight, install a new two-way check valve in accordance with the service bulletin.

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, standardization Branch, ANM–113, FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Standardization Branch, ANM–113.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Standardization Branch, ANM–113.

(c) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Issued in Renton, Washington, on September 17, 1997.

James V. Devany,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 97–25168 Filed 9–22–97; 8:45 am]

BILLING CODE 4910–13–U

SOCIAL SECURITY ADMINISTRATION

20 CFR Part 404

RIN 0960–AE42

Federal Old-Age, Survivors, and Disability Insurance; Determining Disability and Blindness; Revision to Medical-Vocational Guidelines

AGENCY: Social Security Administration.

ACTION: Proposed rules.

SUMMARY: We propose to clarify § 201.00(h) of the medical-vocational guidelines in appendix 2 of subpart P of regulations part 404. This section provides guidance for evaluating disability in individuals under age 50 who have a severe impairment(s) that does not meet or equal in severity the criteria of any listed impairment in appendix 1 of subpart P, but who have a residual functional capacity for no more than the full range of sedentary work and cannot do any past relevant work. The proposed revisions are intended only to clarify the current rules; they are not intended to change any policies.

DATES: To be sure your comments are considered, we must receive them no later than November 24, 1997.

ADDRESSES: Comments should be submitted in writing to the Commissioner of Social Security, P.O. Box 1585, Baltimore, MD 21235, sent by telefax to (410) 966–2830, sent by e-mail to ''regulations@ssa.gov,'' or delivered to the Division of Regulations and Rulings, Social Security Administration, 3–B–1 Operations Building, 6401 Security Boulevard, Baltimore, MD 21235, between 8:00 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.

FOR FURTHER INFORMATION CONTACT: Robert Augustine, Legal Assistant, Division of Regulations and Rulings, Social Security Administration, 6401 Security Boulevard, Baltimore, MD 21235, (410) 966–5121 for information about these rules. For information on eligibility or claiming benefits, call our national toll-free number, 1–800–772–1213.

SUPPLEMENTARY INFORMATION: The Social Security Act (the Act) provides in title II for the payment of disability benefits to workers insured under the Act. Title II also provides, under certain circumstances, child's insurance benefits for persons who become disabled before age 22 and widow's and widower's insurance benefits based on disability for widows, widowers, and surviving divorced spouses of insured individuals. In addition, the Act provides in title XVI for supplemental security income (SSI) payments to persons who are disabled and have limited income and resources.

For adults under both the title II and title XVI programs and for persons claiming child's insurance benefits based on disability under title II, ''disability'' is defined in the Act as the ''inability to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment which can be expected to result in death or which has lasted or can be expected to last for a continuous period of not less than 12 months.'' Sections 223(d) and 1614(a) of the Act also state that the individual ''shall be determined to be under a disability only if his physical or mental impairment or impairments are of such severity that he is not only unable to do his previous work but cannot, considering his age, education, and work experience, engage in any other kind of substantial gainful work which exists in the national economy, regardless of whether such work exists in the immediate area in which he lives, or whether a specific job vacancy exists for him, or whether he would be hired if he applied for work.''

To implement the process for determining whether an individual is disabled based upon this statutory definition, our longstanding regulations at §§ 404.1520 and 416.920 provide for a five-step sequential evaluation process as follows:

1. Is the claimant engaging in substantial gainful activity? If the claimant is working and the work is substantial gainful activity, we find that he or she is not disabled. Otherwise, we proceed to step 2 of the sequence.

2. Does the claimant have an impairment or combination of impairments which is severe? If the claimant does not have an impairment or combination of impairments which is severe, we find that he or she is not disabled. If the claimant has an impairment or combination of impairments which is severe, we proceed to step 3 of the sequence.

3. Does the claimant's severe impairment(s) meet or equal in severity the criteria of a listed impairment in appendix 1 of subpart P of part 404? If so, and the duration requirement is met, we find that he or she is disabled. If not, we proceed to step 4 of the sequence.

4. Does the claimant's severe impairment(s) prevent him or her from doing his or her past relevant work, considering his or her residual functional capacity? If not, we find that he or she is not disabled. If so, we proceed to step 5 of the sequence.

5. Does the claimant's impairment(s) prevent him or her from performing other work that exists in the national economy, considering his or her residual functional capacity, age, education, and work experience? If so, and the duration requirement is met, we find that he or she is disabled. If not, we find that he or she is not disabled.

As discussed in § 404.1569, at step 5 of the sequential evaluation process we provide medical-vocational rules in appendix 2 of subpart P of part 404. (By reference, § 416.969 of the regulations provides that appendix 2 is also applicable to adults claiming SSI payments based on disability.) These rules take administrative notice of the existence of numerous unskilled occupations at exertional levels defined in the regulations, such as ''sedentary,'' ''light,'' and ''medium,'' and, based upon a consideration of the individual's residual functional capacity, age, education, and work experience, either direct decisions or are used as a framework for making decisions at step 5.

The revisions we are proposing would clarify one paragraph in appendix 2, section 201.00(h), which discusses the evaluation of the claims of ''younger individuals'' (i.e., individuals who have not attained age 50) who have a residual functional capacity limited to the full range of sedentary work administratively noticed by the rules in table No. 1 of appendix 2 or who can perform some sedentary work but not the full range of such work.

Summary of Proposed Changes

We propose to clarify section 201.00(h) in appendix 2. This section discusses the evaluation of disability claims of ''younger individuals'' (i.e., individuals who have not attained age 50) who have a severe impairment(s) that does not meet or equal in severity the criteria of any listing but who have a residual functional capacity for no more than the full range of sedentary work. The proposed changes are intended only as clarifications. None of these proposed revisions is intended to change the meaning of the current rules.

Specifically, we propose to clarify the second sentence of section 201.00(h) in appendix 2, which states that for workers who are age 45–49, ''age is a less positive factor'' than for individuals who are younger than age 45. The proposed clarification would more clearly explain that, for workers who are age 45–49, age is a ''less advantageous factor for making an adjustment to other work than for those who are age 18–44.'' This is consistent with our longstanding policy that, at step 5 of the sequential evaluation process, the issue is whether the individual is able to make an adjustment to work other than any past relevant work considering his or her residual functional capacity, age, education, and work experience, and would only clarify what we mean by the phrase ''a less positive factor.''

In the third sentence, clause (3), we propose to change the phrases ''relevant past work'' and ''vocationally relevant past work,'' to ''past relevant work'' to clarify our intended meaning and for consistency in our terminology. We also propose to clarify clause (4) of the same sentence to better explain that the term ''illiterate'' means that the individual is illiterate in English. This will make clearer our original intent that the fourth clause describes individuals who are either 1) unable to communicate in English (and, by definition, illiterate in English) or 2) able to speak and understand English but illiterate in English.

We propose to revise the fourth sentence to be consistent with the foregoing proposed revisions. We propose to revise the statement ''age is a more positive factor for those who are under age 45'' to ''for those who are under age 45, age is a more advantageous factor for making an adjustment to other work'' to correspond to the proposed changes in the second sentence. Likewise, we propose to clarify that ''illiterate'' means illiterate in English as in the proposed changes to the third sentence.

We propose to add four new sentences after the fifth sentence to explain the impact of a maximum sustained work capacity for no more than the full range of sedentary work on an individual's ability to do other work. The intent is twofold: 1) to make clear that such capacity reflects a very serious functional limitation and must be appropriately documented by the evidence in the record; and 2) to make clear that a finding that an individual is limited to less than the full range of sedentary work does not necessarily equate with a finding of disability. If an individual is unable to perform past relevant work and has a maximum sustained work capacity for less than the full range of sedentary work (and the medical-vocational rules would not direct a decision of disabled if the individual was limited to the full range of sedentary work), consideration must still be given to whether there is other work in the national economy that the individual is able to do.

We also propose to add language to the fifth sentence to make it explicitly clear that a finding of ''disabled'' is also not precluded for individuals age 45–49 who do not meet all of the criteria of a specific rule and who do not have the ability to perform a full range of sedentary work.

We also propose to delete without replacement the two case examples from section 201.00(h). The intent of these examples is merely to reinforce a concept already reflected in this paragraph; i.e., that, using the rules as a framework for decisionmaking, a conclusion of ''disabled'' may be, but is not necessarily, warranted for individuals under age 45 who do not satisfy all of the criteria of a specific rule and who do not have the residual functional capacity to do a full range of sedentary work.

We propose to delete the examples because they are no longer needed and our adjudicative experience has shown that they can be unclear. For example, we have received questions about whether example 2 applies only to cases involving mental impairments or whether it could apply to other types of impairments. Although our intent has always been that the case examples are applicable to all types of impairments, their removal will avoid possible confusion and help ensure consistency in decisionmaking.

In addition, over the past several years we have been following a practice of not using case examples in our disability regulations unless they serve some necessary purpose, such as when the rules present a new and complex policy where we believe that an example or examples would be helpful for understanding the new policy. We believe the examples in the current rules no longer serve such a purpose and that it is better to delete them. Again, this is not intended as a change in policy.

Finally, we are also making minor editorial changes, to improve the consistency of terminology in appendix 2.

Regulatory Procedures

Executive Order 12866

We have consulted with the Office of Management and Budget (OMB) and determined that these proposed rules meet the criteria for a significant regulatory action under Executive Order 12866. Thus, they were subject to OMB review. There are no program or administrative costs or savings associated with these proposed rules. Therefore, no assessment of costs and benefits is required.

Regulatory Flexibility Act

We certify that these proposed regulations will not have a significant economic impact on a substantial number of small entities because they affect only individuals. Therefore, a regulatory flexibility analysis, as provided in Public Law 96–354, the Regulatory Flexibility Act, is not required.

Paperwork Reduction Act

These proposed regulations will impose no new reporting or recordkeeping requirements requiring OMB clearance.

(Catalog of Federal Domestic Assistance Program Nos. 96.001, Social Security Disability Insurance; 96.006, Supplemental Security Income)

List of Subjects in 20 CFR Part 404

Administrative practice and procedure, Blind, Death benefits, Disability benefits, Old-Age, Survivors and Disability Insurance, Reporting and recordkeeping requirements, Social Security.

Dated: June 16, 1997.

John J. Callahan,

Acting Commissioner of Social Security.

For the reasons set out in the preamble, part 404, subpart P, Chapter III of Title 20, Code of Federal Regulations, is proposed to be amended as set forth below.

PART 404—FEDERAL OLD-AGE, SURVIVORS AND DISABILITY INSURANCE (1950–)

1. The authority citation for subpart P continues to read as follows:

Authority: Secs. 202, 205(a), (b), and (d)–(h), 216(i), 221(a) and (i), 222(c), 223, 225, and 702(a)(5) of the Social Security Act (42 U.S.C. 402, 405(a), (b), and (d)–(h), 416(i), 421(a) and (i), 422(c), 423, 425, and 902(a)(5)); sec. 211(b), Pub. L. 104–193, 110 Stat. 2105, 2189.

2. Section 201.00(h), appendix 2, subpart P, is revised to read as follows:

APPENDIX 2 TO SUBPART P—MEDICAL-VOCATIONAL GUIDELINES

* * * * *

201.00 Maximum sustained work capability limited to sedentary work as a result of severe medically determinable impairment(s).

* * * * *

(h) The term *younger individual* is used to denote an individual age 18 through 49. For individuals who are age 45–49, age is a less advantageous factor for making an adjustment to other work than for those who are age 18–44. Accordingly, for such individuals who: (1) are restricted to sedentary work, (2) are unskilled or have no transferable skills, (3) have no past relevant work or who can no longer perform past relevant work, and (4) are unable to communicate in English, or are able to speak and understand English but are illiterate in English, a finding of ''disabled'' is warranted. For individuals who are under age 45, age is a more advantageous factor for making an adjustment to other work and is usually not a significant factor in limiting such individuals' ability to make an adjustment to other work, even an adjustment to unskilled sedentary work, and even when the individuals are unable to communicate in English or are illiterate in English. A finding of ''disabled'' is not precluded for those individuals under age 45 (and those age 45–49 for whom rule 201.17 does not direct a decision of disabled) who do not meet all of the criteria of a specific rule and who do not have the ability to perform a full range of sedentary work. However, the inability to perform the full range of sedentary work does not necessarily equate with a finding of ''disabled.'' In deciding whether an individual who is limited to a partial range of sedentary work is able to make an adjustment to work other than any past relevant work, the adjudicator is required to make an individualized determination considering the individual's remaining occupational base, age, education, and work experience. Further, ''sedentary work'' represents a significantly restricted range of work, and individuals with a maximum sustained work capability limited to sedentary work have very serious functional limitations. Therefore, a finding that an individual is limited to less than the full range of sedentary work will be based on a careful consideration of the evidence of an individual's medical impairment(s) and the limitations and restrictions attributable thereto. Such evidence must support the finding that an individual's residual functional capacity is limited to less than the full range of sedentary work.

* * * * *

[FR Doc. 97–25125 Filed 9–22–97; 8:45 am]

BILLING CODE 4190–29–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 200

[Docket No. 96N–0048]

Sterility Requirements for Inhalation Solution Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulations to require that all inhalation solutions for nebulization be sterile. Inhalation solutions for nebulization, as the term is used in this document, refers to inhalation solutions administered as a fine aqueous mist created by an atomizer or nebulizer. Currently, approximately half of these products are manufactured to be sterile. Based on reports of adverse drug experiences from contaminated nonsterile inhalation solutions for nebulization and recalls of these products, FDA is taking this action to ensure the safety and effectiveness of these solutions.

DATES: Written comments by December 22, 1997. Submit written comments on the information collection requirements by October 23, 1997. FDA proposes that any final rule that may issue based on this proposal become effective March 23, 1998.

ADDRESSES: Submit written comments on this proposed rule to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Submit written comments on the information collection requirements to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

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

SUPPLEMENTARY INFORMATION:

I. Background

Inhalation solutions for nebulization are used to treat a variety of breathing disorders. Currently, approximately half of the marketed products are manufactured to be sterile. Those products not manufactured to be sterile are often manufactured under assigned