

requirements, Supplemental Security Income.

Dated: July 22, 2003.

Jo Anne B. Barnhart,
Commissioner of Social Security.

■ For the reasons set forth in the preamble, subpart P of part 404 of chapter III of title 20 of the Code of Federal Regulations is amended as set forth below:

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

■ 1. The authority citation for subpart P of part 404 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.

Appendix 1 to Subpart P of Part 404—[Amended]

■ 2. Add new section 11.00G to section 11.00 in part A of appendix 1 and revise section 11.10 to read as follows:

Appendix 1 to Subpart P of Part 404—Listing of Impairments

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11.00 Neurological

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G. *Amyotrophic Lateral Sclerosis (ALS)*. 1. Amyotrophic lateral sclerosis (ALS), sometimes called Lou Gehrig's disease, is a progressive, invariably fatal neurological disease that attacks the nerve cells (motor neurons) responsible for controlling voluntary muscles. Eventually, all muscles under voluntary control are affected, and individuals with ALS ultimately lose their ability to move their arms and legs, and their capacity to swallow, speak, and breathe. Most people with ALS die from respiratory failure. There is currently no cure for ALS, and most treatments are designed only to relieve symptoms and improve the quality of life.

2. Diagnosis of ALS is based on history, neurological findings consistent with the diagnosis of ALS, and electrophysiological and neuroimaging testing to rule out other impairments that may cause similar signs and symptoms. The diagnosis may also be supported by electrophysiological studies (electromyography or nerve conduction studies), but these tests may be negative or only suggestive of the diagnosis. There is no single test that establishes the existence of ALS.

3. For purposes of 11.10, documentation of the diagnosis must be by generally accepted methods consistent with the prevailing state of medical knowledge and clinical practice. The evidence should include documentation of a clinically appropriate medical history, neurological findings consistent with the diagnosis of ALS, and the results of any

electrophysiological and neuroimaging testing.

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11.10 *Amyotrophic lateral sclerosis* established by clinical and laboratory findings, as described in 11.00G.

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PART 416—SUPPLEMENTAL SECURITY INCOME FOR THE AGED, BLIND, AND DISABLED

■ 3. The authority citation for subpart I of part 416 continues to read as follows:

Authority: Secs. 702(a)(5), 1611, 1614, 1619, 1631(a), (c), and (d)(1), and 1633 of the Social Security Act (42 U.S.C. 902(a)(5), 1382, 1382c, 1382h, 1383(a), (c), and (d)(1), and 1383b); secs. 4(c) and 5, 6(c)—(e), 14(a), and 15, Pub. L. 98–460, 98 Stat. 1794, 1801, 1802, and 1808 (42 U.S.C. 421 note, 423 note, 1382h note).

■ 4. In § 416.934, revise paragraph (g) and add new paragraph (i) to read as follows:

§ 416.934 Impairments which may warrant a finding of presumptive disability or presumptive blindness.

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(g) Allegation of Down syndrome.

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(i) Allegation of amyotrophic lateral sclerosis (ALS, Lou Gehrig's disease).

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 2003N–0346]

Food Labeling: Ingredient Labeling of Dietary Supplements That Contain Botanicals

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulation on declaring botanical ingredients in dietary supplements to incorporate by reference the latest editions of two books. Currently, the regulation incorporates by reference *Herbs of Commerce* (1992) and the *International Code of Botanical Nomenclature (Tokyo Code) 1994*. FDA is replacing the references to these editions with the 2000 editions of the same books. This action is intended to provide industry with current and more comprehensive references to use in

identifying on product labels the common or usual name of each botanical ingredient contained in dietary supplements. In addition, FDA is incorporating new statutory restrictions on the use of the word “ginseng” in dietary supplement labeling. Finally, FDA is making minor wording changes in its regulation on declaring botanical ingredients in dietary supplements. These changes are intended to improve the reader's understanding, consistent with the principles of plain English, or to be more technically accurate, consistent with internationally accepted botanical terminology. FDA is issuing a direct final rule for this action because FDA expects there will be no significant adverse comments on the rule. Elsewhere in this issue of the **Federal Register**, FDA is publishing a companion proposed rule through the usual notice-and-comment rulemaking process. If FDA receives significant adverse comment on either rule, FDA intends to withdraw the direct final rule and proceed with the rulemaking. The companion proposed rule and direct final rule are substantively identical.

DATES: This rule is effective January 1, 2006. Submit written or electronic comments on this direct final rule by November 12, 2003. If FDA receives no significant adverse comments within the specified comment period, the agency intends to publish a document in the **Federal Register** confirming the effective date of this direct final rule. If the agency receives any timely significant adverse comments, FDA intends to publish a document in the **Federal Register** withdrawing this direct final rule before its effective date. The Director of the Office of the Federal Register approves the incorporation by reference, in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, of certain publications in 21 CFR 101.4(h) as of January 1, 2006.

ADDRESSES: Submit written comments on this direct final rule to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: Victoria Lutwak, Office of Nutritional Products, Labeling, and Dietary Supplements, Center for Food Safety and Applied Nutrition (HFS–810), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2375.

SUPPLEMENTARY INFORMATION: