and equitable method, please identify what alternative methodology is fair and equitable, and explain why, providing, where possible, empirical evidence to support any proposed methodology.

(C) For any such alternative methodology, please identify, with specificity, what entities should be assessed electric annual charges and how such an alternative methodology would work,[36] including what data the Commission would need to allocate the charges and how the Commission would obtain the data.

III. Comment Procedures

24. The Commission invites interested persons to submit comments on the matters and inquiries discussed in this notice, including any related matters or alternative proposals that commenters may wish to discuss. Comments are due May 28, 2008. Comments must refer to Docket No. AD08–7–000, and must include the commenter's name, the organization it represents, if applicable, and its address in their comments.

25. The Commission encourages comments to be filed electronically via the eFiling link on the Commission's Web site at *http://www.ferc.gov*. The Commission accepts most standard word processing formats. Documents created electronically using word processing software should be filed in native applications or print-to-PDF format and not in a scanned format. Commenters filing electronically do not need to make a paper filing.

26. Commenters that are not able to file comments electronically must send an original and 14 copies of their comments to: Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street, NE., Washington, DC 20426.

27. All comments will be placed in the Commission's public files and may be viewed, printed, or downloaded remotely as described in the Document Availability section below. Commenters are not required to serve copies of their comments on other commenters.

IV. Document Availability

28. In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the Internet through the Commission's Home Page (*http://www.ferc.gov*) and in the Commission's Public Reference Room during normal business hours (8:30 a.m. to 5 p.m. Eastern time) at 888 First Street, NE., Room 2A, Washington, DC 20426.

29. From the Commission's Home Page on the Internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

30. User assistance is available for eLibrary and the Commission's Web site during normal business hours from FERC Online Support at (202) 502–6652 (toll free at (866) 208–3676) or e-mail at *ferconlinesupport@ferc.gov*, or the Public Reference Room at (202) 502–8371, TTY (202) 502–8659. E-mail the Public Reference Room at *public.referenceroom@ferc.gov*.

By direction of the Commission.

Kimberly D. Bose,

Secretary.

[FR Doc. E8–9199 Filed 4–25–08; 8:45 am]

BILLING CODE 6717–01–P

[36] The Commission emphasizes the importance of this third question. Parties seeking a change in methodology are cautioned to give this question careful thought and thorough analysis. Broadly phrased requests that some other entities be charged will be less persuasive than specific recommendations as to which particular entities should be charged, and how.

SOCIAL SECURITY ADMINISTRATION

20 CFR Part 404

[Docket No. SSA–2007–0066]

RIN 0960–AG57

Revised Medical Criteria for Evaluating Malignant Neoplastic Diseases

AGENCY: Social Security Administration.

ACTION: Notice of proposed rulemaking.

SUMMARY: We propose to revise the criteria in parts A and B of the Listing of Impairments (the listings) that we use to evaluate claims involving malignant neoplastic diseases. We apply these criteria when you claim benefits based on disability under title II and title XVI of the Social Security Act (the Act). The proposed revisions reflect our adjudicative experience, as well as advances in medical knowledge, treatment, and methods of evaluating malignant neoplastic diseases.

DATES: To be sure that your comments are considered, we must receive them by *June 27, 2008*.

ADDRESSES: You may submit comments by any of the following methods. Regardless of which method you choose, to ensure that we can associate your comments with the correct regulation for consideration, state that your comments refer to Docket No. SSA–2007–0066:

- Federal eRulemaking Portal at *http://www.regulations.gov*. (This is the preferred method for submitting your comments.) In the Comment or Submission section, type ''SSA–2007–0066'', select ''Go'', and then click ''Send a Comment or Submission'' under the highlighted SSA–2007–00766 text.
- Telefax to (410) 966–2830.
- Letter to the Commissioner of Social Security, P.O. Box 17703, Baltimore, MD 21235–7703.
- Deliver your comments to the Office of Regulations, Social Security Administration, 922 Altmeyer Building, 6401 Security Boulevard, Baltimore, MD 21235–6401, between 8 a.m. and 4:30 p.m. on regular business days.

Comments are posted on the Federal eRulemaking Portal, or you may inspect them on regular business days by making arrangements with the contact person shown in this preamble.

FOR FURTHER INFORMATION CONTACT: Rosemarie Greenwald, Social Insurance Specialist, Social Security Administration, Office of Regulations, 960 Altmeyer Building, 6401 Security Boulevard, Baltimore, MD 21235–6401. Call 410–966–7813 for further information about these proposed rules. For information on eligibility or filing for benefits, call our national toll-free number 1–800–772–1213 or TTY 1–800–325–0778, or visit our Internet Web site, Social Security Online, at *http://www.socialsecurity.gov*.

SUPPLEMENTARY INFORMATION:

Electronic Version

The electronic file of this document is available on the date of publication in the **Federal Register** at *http://www.gpoaccess.gov/fr/index.html*.

Why are we proposing to revise the adult listings for malignant neoplastic diseases?

We last published final rules revising the listings for malignant neoplastic diseases in the **Federal Register** on November 15, 2004 (69 FR 67017, corrected at 70 FR 15227). In those rules, we indicated that we intended to monitor these listings and to update the criteria for any malignant neoplastic disease contained in these listings as the need arose. We are proposing changes to the listing criteria for malignant neoplastic diseases to reflect our adjudicative experience since we last issued final rules on this body system and to reflect advances in medical knowledge, treatment, and methods of evaluating malignant neoplastic diseases. We are also proposing changes to the introductory text to these listings

to provide additional information about how we evaluate malignant neoplastic diseases and to update medical terminology. Many of these proposed changes are based on the answers we provided to our adjudicators who had questions about the current rules.

How do we propose to revise the introductory text to the malignant neoplastic diseases listings for adults?

We propose to make the following changes to 13.00I, ''What do these terms in the listings mean?''

- Expand the definition of ''inoperable'' in current 13.00I1 by adding a reference to the term ''neoadjuvant therapy'' and defining it. ''Neoadjuvant therapy'' is antineoplastic therapy, such as chemotherapy or radiation, that you receive before surgery in order to reduce the size of your tumor. In current 13.00I1, we explain that the determination of whether a tumor is inoperable ''usually occurs before attempts to shrink the tumor with chemotherapy or radiation''; that is, before the administration of neoadjuvant therapy. However, it is becoming more common in medical practice to wait until neoadjuvant therapy is completed before determining whether a tumor is inoperable. Therefore, we propose to revise current 13.00I1 to define the term ''neoadjuvant therapy'' and to explain that the determination of whether a tumor is inoperable ''may be made before or after neoadjuvant therapy,'' to be consistent with current medical practice. Lastly, we propose to make minor editorial changes to clarify our list of examples of when a tumor may be considered inoperable.
- Expand the definition of ''unresectable'' in current 13.00I2 (proposed 13.00I6) by defining the term ''adjuvant therapy'' and explaining how the use of this type of therapy relates to a determination of whether a tumor is unresectable. ''Adjuvant therapy'' is antineoplastic therapy, such as chemotherapy or radiation, that you receive after you have surgery in order to eliminate any remaining cancer cells and lessen the chance of recurrence.
- Add a definition for ''metastases'' (proposed 13.00I2). In the proposed definition, we explain that ''metastases'' means spread of tumor cells by blood, lymph, or other body fluid. We also explain that ''metastases'' does not include the spread of tumor cells by direct extension of the tumor to other tissue or organs.
- Reorganize the section to present the terms in alphabetical order for easier reference.

We propose to make the following changes to 13.00K, ''How do we evaluate specific malignant neoplastic diseases?''

- Revise current 13.00K1a and 13.00K1b to refer to ''indolent lymphoma'' instead of ''low grade or indolent lymphoma'' to reflect current medical terminology.
- Expand current 13.00K2a to recognize that testicular biopsy is an acceptable method of documenting recurrent leukemia.
- Revise current 13.00K6 to clarify that we consider a brain tumor to be malignant if it is classified as grade II or higher under the World Health Organization's (WHO's) classification of tumors of the central nervous system published in 2007. (See References at the end of this preamble.) For purposes of determining disability, we do not consider grade I tumors to be malignant because they are usually associated with long-term survival, even in the rare situation in which they progress or recur following initial antineoplastic therapy. Although we would not evaluate grade I brain tumors under the listings for malignant neoplastic diseases, we would evaluate them under listing 11.05.

How do we propose to revise the criteria in the malignant neoplastic listings for adults?

We propose to revise current listing 13.02C, which applied to recurrent soft tissue tumors of the head and neck, except for salivary or thyroid gland tumors. The current listing excludes local vocal cord recurrence. We propose to revise the listing to specify that it does not include ''recurrence in the true vocal cord.'' The proposed change more accurately reflects our intent. Accordingly, under our proposal as under our current rules, recurrence of the disease in the ''false'' vocal cord would meet listing 13.02C.

We propose to expand the criteria in current listing 13.03B2 for melanoma with palpable nodal metastases or metastases to adjacent skin (satellite lesions) or elsewhere. A palpable lymph node is a type of ''clinically apparent'' lymph node. As defined by the American Joint Committee on Cancer (AJCC) in the sixth edition of the Cancer Staging Handbook (see References at the end of this preamble), ''clinically apparent'' means ''detected by imaging studies (excluding lymphoscintigraphy) or by clinical examination.'' Current medical literature establishes that a finding of melanoma with metastases to one or more ''clinically apparent'' lymph nodes is equivalent in severity to palpable nodal metastases. The literature also establishes that a finding of melanoma with metastases to four or more lymph nodes that are not clinically apparent is equivalent in severity to palpable nodal metastases. Therefore, we propose to expand the current listing to include these criteria. We also propose to make a minor editorial change to clarify that ''elsewhere'' means ''distant sites.''

We propose to make the following changes to current listing 13.05A for non-Hodgkin's lymphoma:

- Replace the terms ''intermediate or high-grade'' and ''low-grade or indolent'' with the terms ''aggressive'' and ''indolent,'' respectively, to reflect current medical terminology;
- Clarify that mycosis fungoides is an indolent lymphoma by removing it from the heading of the listing and including it as an example in proposed listing 13.05A2; and
- Add an example of an aggressive lymphoma and another example of an indolent lymphoma for clarity.

Current listing 13.09B, for carcinoma of the thyroid gland with metastases beyond the regional lymph nodes, provides that we consider this disease to be of listing-level severity when it progresses despite radioactive iodine treatment. We propose to add a criterion, proposed listing 13.09C, for medullary carcinoma of the thyroid gland with metastases beyond the regional lymph nodes. Because medullary carcinoma is not treated with radioactive iodine, it cannot meet current listing 13.09B.

Although we are adding this criterion for adults, we are not adding a comparable criterion for children since medullary carcinoma is extremely rare in children. Instead, we are proposing to include guidance in proposed 113.00K4, the introductory text to the childhood listings, indicating that we will use listing 13.09C in the rare case in which a child has medullary carcinoma of the thyroid gland.

When we published current listing 13.10B, for breast carcinoma, the spread of breast carcinoma to the supraclavicular nodes was considered to be distant metastases. However, the medical community no longer considers this to represent distant metastases for breast carcinoma. Therefore, we propose to add a criterion to current listing 13.10B for metastases to the supraclavicular nodes to make it clear that we will continue to consider metastases to the supraclavicular nodes to be of listing-level severity.

We also propose to add criteria for breast cancer with metastases to the infraclavicular nodes or to 10 or more axillary nodes. In light of the current

medical literature, we believe that these findings are indicative of listing-level severity as well.

We propose to remove the words ''carcinoma or'' from the heading of current listing 13.11, for malignant neoplastic diseases of the skeletal system, to correct an editorial error. A carcinoma is a malignant tumor that begins in the skin or in tissues that line or cover internal organs. Therefore, by definition, a carcinoma cannot originate in the skeletal system.

We propose to make a minor editorial change to current listing 13.13A1 for highly malignant central nervous system neoplasms to clarify that the requirement for documented metastases applies only to medulloblastoma or other primitive neuroectodermal tumors (PNETs), and not to grades III and IV astrocytomas, glioblastoma multiforme, and ependymoblastoma. This is what we intend in the current rule, but we wanted to make the current sentence structure clearer. Therefore, we propose to reorganize the sentence for clarity. We also propose to add the word ''malignant'' to current listing 13.13A, for central nervous system neoplasms. This would clarify that we do not evaluate benign tumors under this listing.

We propose to expand the criteria in current listing 13.14, for carcinoma of the lungs, by adding proposed listing 13.14C. The proposed listing would provide that an individual with carcinoma of the superior sulcus (including Pancoast tumors) who receives multimodal antineoplastic therapy would be disabled for at least 18 months from the date of diagnosis. This criterion recognizes the debilitating effects of, and the length of time needed to recover from, treatment for this disease. At the end of the 18-month period, we would evaluate any residual impairment(s) under the criteria for the affected body system.

We propose to remove current listing 13.23E1c, for ovarian cancer with ruptured ovarian capsule, tumor on the serosal surface of the ovary, ascites with malignant cells, or positive peritoneal washings. Current medical literature indicates improved prognoses for these clinical findings. Consequently, we believe that these clinical findings do not usually represent an impairment of listing-level severity. We will continue to consider ovarian cancer to be of listing-level severity if it meets the other criteria in current listing 13.23E1; that is, there is tumor extension beyond the pelvis (current listing 13.23E1a), there are metastases to or beyond the regional lymph nodes (current listing 13.23E1b), or the disease is recurrent following initial antineoplastic therapy (current listing 13.23E1d). Because of this proposed deletion, we would redesignate current listing 13.23E1d as listing 13.23E1c.

We propose to revise listing 13.24B for carcinoma of the prostate gland to clarify that ''visceral metastases'' means metastases to internal organs.

We propose to make a minor editorial change to current listing 13.27 for malignant tumors for which the primary site of origin is unknown. The current listing provides that these tumors are of listing-level severity ''except for solitary squamous cell carcinoma in the neck.'' We propose to revise this language to read ''except for squamous cell carcinoma confined to the neck nodes'' for clarity.

How do we propose to revise the introductory text to the malignant neoplastic diseases listings for children?

We propose to make the following changes in 113.00 to correspond to changes we propose to make in 13.00:

- Add a definition of ''metastases'' (proposed 113.00I1);
- Reorganize section 113.00I to present the terms in alphabetical order for easier reference;
- Revise the guidance on lymphoma in current 113.00K1a to refer to ''aggressive'' lymphoma and ''indolent'' lymphoma and to make minor editorial changes;
- Revise current 113.00K2a to add testicular biopsy as an acceptable method of documenting recurrent leukemia; and
- Revise current 113.00K4 (proposed 113.00K5) to clarify when we consider a brain tumor to be malignant.

We also propose to add a new 113.00K4 to provide guidance on evaluating thyroid tumors. As we indicated above, we are not proposing to add a listing for medullary carcinoma of the thyroid gland to the childhood listings because this disease is extremely rare in children. Instead, we propose to add guidance indicating that we will evaluate this disease in children under listing 13.09C. Because of this addition, we would redesignate current 113.00K4 and current 113.00K5 as 113.00K5 and 113.00K6.

How do we propose to revise the criteria in the malignant neoplastic listings for children?

We propose to revise current listing 113.13, for brain tumors, to be consistent with the change we are proposing in current listing 13.13A1.

What programs would these proposed regulations affect?

These proposed rules would affect disability determinations and decisions that we make under titles II and XVI of the Act. In addition, to the extent that Medicare entitlement and Medicaid eligibility are based on whether you qualify for disability benefits under title II or title XVI, these proposed rules would also affect the Medicare and Medicaid programs.

Who can get disability benefits?

Under title II of the Act, we provide for the payment of disability benefits if you are disabled and belong to one of the following three groups:

- Workers insured under the Act,
- Children of insured workers, and
- Widows, widowers, and surviving divorced spouses (see § 404.336) of insured workers.

Under title XVI of the Act, we provide for supplemental security income (SSI) payments on the basis of disability if you are disabled and have limited income and resources.

How do we define disability?

Under both the title II and title XVI programs, disability must be the result of any medically determinable physical or mental impairment or combination of impairments that is expected to result in death or which has lasted or can be expected to last for a continuous period of at least 12 months. Our definitions of disability are shown in the following table:

If you file a claim under * * *	And you are * * *	Disability means you have a medically determinable impairment(s) as described above that results in * * *
title II	an adult or a child	the inability to do any substantial gainful activity (SGA).
title XVI	an individual age 18 or older	the inability to do any SGA.
title XVI	an individual under age 18	marked and severe functional limitations.

How do we decide whether you are disabled?

If you are applying for benefits under title II of the Act, or if you are an adult applying for payments under title XVI of the Act, we use a five-step ''sequential evaluation process'' to decide whether you are disabled. We describe this five-step process in our regulations at §§ 404.1520 and 416.920. We follow the five steps in order and stop as soon as we can make a determination or decision. The steps are:

1. Are you working, and is the work you are doing substantial gainful activity? If you are working and the work you are doing is substantial gainful activity, we will find that you are not disabled, regardless of your medical condition or your age, education, and work experience. If you are not, we will go on to step 2.

2. Do you have a ''severe'' impairment? If you do not have an impairment or combination of impairments that significantly limits your physical or mental ability to do basic work activities, we will find that you are not disabled. If you do, we will go on to step 3.

3. Do you have an impairment(s) that meets or medically equals the severity of an impairment in the listings? If you do, and the impairment(s) meets the duration requirement, we will find that you are disabled. If you do not, we will go on to step 4.

4. Do you have the residual functional capacity (RFC) to do your past relevant work? If you do, we will find that you are not disabled. If you do not, we will go on to step 5.

5. Does your impairment(s) prevent you from doing any other work that exists in significant numbers in the national economy, considering your RFC, age, education, and work experience? If it does, and it meets the duration requirement, we will find that you are disabled. If it does not, we will find that you are not disabled.

We use a different sequential evaluation process for children who apply for payments based on disability under SSI. If you are already receiving benefits, we also use a different sequential evaluation process when we decide whether your disability continues. See §§ 404.1594, 416.924, 416.994, and 416.994a of our regulations. However, all of these processes include steps at which we consider whether your impairment(s) meets or medically equals one of our listings.

What are the listings?

The listings are examples of impairments that we consider severe enough to prevent you as an adult from doing any gainful activity. If you are a child seeking SSI payments based on disability, the listings describe impairments that we consider severe enough to result in marked and severe functional limitations. Although the listings are contained only in appendix 1 to subpart P of part 404 of our regulations, we incorporate them by reference in the SSI program in § 416.925 of our regulations and apply them to claims under both title II and title XVI of the Act.

How do we use the listings?

The listings are in two parts. There are listings for adults (part A) and for children (part B). If you are an individual age 18 or over, we apply the listings in part A when we assess your claim, and we never use the listings in part B.

If you are an individual under age 18, we first use the criteria in part B of the listings. Part B contains criteria that apply only to individuals who are under age 18. If the criteria in part B do not apply, we may use the criteria in part A when those criteria give appropriate consideration to the effects of the impairment(s) in children. (See §§ 404.1525 and 416.925.)

If your impairment(s) does not meet any listing, we will also consider whether it medically equals any listing; that is, whether it is as medically severe as an impairment in the listings. (See §§ 404.1526 and 416.926.)

What if you do not have an impairment(s) that meets or medically equals a listing?

We use the listings only to decide that you are disabled or that you are still disabled. We will not deny your claim or decide that you no longer qualify for benefits because your impairment(s) does not meet or medically equal a listing. If you have a severe impairment(s) that does not meet or medically equal any listing, we may still find you disabled based on other rules in the ''sequential evaluation process.'' Likewise, we will not decide that your disability has ended only because your impairment(s) no longer meets or medically equals a listing.

Also, when we conduct reviews to determine whether your disability continues, we will not find that your disability has ended because we have changed a listing. Our regulations explain that, when we change our listings, we continue to use our prior listings when we review your case, if you qualified for disability benefits or SSI payments based on our determination or decision that your impairment(s) met or medically equaled a listing. In these cases, we determine whether you have experienced medical improvement, and if so, whether the medical improvement is related to the ability to work. If your condition(s) has medically improved so that your impairment(s) no longer meets or medically equals the prior listing, we evaluate your case further to determine whether you are currently disabled. We may find that you are currently disabled, depending on the full circumstances of your case. See §§ 404.1594(c)(3)(i) and 416.994(b)(2)(iv)(A). If you are a child who is eligible for SSI payments, we follow a similar rule when we decide that you have experienced medical improvement in your condition(s). See § 416.994a(b)(2).

When will we start to use these rules?

We will not use these rules until we evaluate the public comments we receive on them, determine whether they should be issued as final rules, and issue final rules in the **Federal Register**. If we publish final rules, we will explain in the preamble how we will apply them, and summarize and respond to the public comments. Until the effective date of any final rules, we will continue to use our current rules.

How long would these proposed rules be effective?

If we publish these proposed rules as final rules, they will remain in effect for 8 years after the date they become effective, unless we extend them, or revise and issue them again.

Clarity of these Proposed Rules

Executive Order 12866, as amended, requires each agency to write all rules in plain language. In addition to your substantive comments on these proposed rules, we invite your comments on how to make them easier to understand.

For example:

- Have we organized the material to suit your needs?
- Are the requirements in the rules clearly stated?
- Do the rules contain technical language or jargon that is not clear?
- Would a different format (grouping and order of sections, use of headings, paragraphing) make the rules easier to understand?
- Would more (but shorter) sections be better?
- Could we improve clarity by adding tables, lists, or diagrams?
- What else could we do to make the rules easier to understand?

Regulatory Procedures

Executive Order 12866

We have consulted with the Office of Management and Budget (OMB) and determined that these proposed rules meet the requirements for a significant regulatory action under Executive Order 12866, as amended. Thus, they were subject to OMB review.

The Office of the Chief Actuary estimates that these proposed rules, if finalized, would reduce the program costs of the Old Age, Survivors, and Disability Insurance (OASDI) and the SSI programs, as shown in the table below:

ESTIMATED NET REDUCTIONS IN OASDI BENEFIT PAYMENTS AND FEDERAL SSI PAYMENTS DUE TO THE PROPOSED REVISION OF THE MALIGNANT NEOPLASTIC DISEASES LISTINGS, FISCAL YEARS 2009–2018

(in millions)

Fiscal year	OASDI	SSI
2009	$1	(1)
2010	2	(1)
2011	2	(1)
2012	3	$1
2013	4	1
2014	5	1
2015	6	1
2016	7	1
2017	8	1
2018	9	1
Totals:		
2019–2013	12	2
2009–2018	47	8

[1] Reduction in payments of less than $500,000.

Regulatory Flexibility Act

We certify that these proposed rules would not have a significant economic impact on a substantial number of small entities because they would affect only individuals. Thus, a regulatory flexibility analysis as provided in the Regulatory Flexibility Act, as amended, is not required.

Paperwork Reduction Act

These proposed rules will impose no additional reporting or recordkeeping requirements requiring OMB clearance.

References

During development of these proposed rules, we consulted the following information:

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Morton, D.L. and Cochran, A.J., The case for lymphatic mapping and sentinel lymphadenectomy in the management of primary melanoma, *British Journal of Dermatology*, Aug;151(2), 308–319 (2004).

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These references are included in the rulemaking record for these proposed rules and are available for inspection by interested individuals making arrangements with the contact person shown in this preamble.

(Catalog of Federal Domestic Program Nos. 96.001, Social Security—Disability Insurance; 96.002, Social Security—Retirement Insurance; 96.004, Social Security—Survivors Insurance; and 96.006, Supplemental Security Income)

List of Subjects in 20 CFR Part 404

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

Dated: January 29, 2008.

Michael J. Astrue,

Commissioner of Social Security.

For the reasons set out in the preamble, we propose to amend Appendix 1 to subpart P of part 404 of chapter III of title 20 of the Code of Federal Regulations 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; sec. 202, Pub. L. 108–203, 118 Stat. 509 (42 U.S.C. 902 note).

2. Appendix 1 to subpart P of Part 404 is amended as follows:

a. Revise the expiration date in item 14 of the introductory text before part A of appendix 1.

b. Revise paragraph I of section 13.00 of part A of appendix 1.

c. Amend paragraph K of section 13.00 of part A of appendix 1 by revising 13.00K1a, 13.00K1b, the third sentence of 13.00K2a, and 13.00K6.

d. Revise listing 13.02C of part A of appendix 1.

e. Revise listing 13.03B2 of part A of appendix 1.

f. Amend listing 13.05 of part A of appendix 1 by revising the heading and listing 13.05A.

g. Amend listing 13.09 of part A of appendix 1 by adding the word ''OR'' and listing 13.09C.

h. Revise listing 13.10B of part A of appendix 1.

j. Amend listing 13.11 of part A of appendix 1 by removing the words ''carcinoma or.''

k. Revise listings 13.13A1 and 13.13A2 of part A of appendix 1.

l. Amend listing 13.14 of part A of appendix 1 by adding the word ''OR'' and listing 13.14C.

m. Amend listing 13.23 of part A of appendix 1 by removing current listing 13.23E1c and redesignating current listing 13.23E1d as listing13.23E1c.

n. Revise listing 13.24B of part A of appendix 1.

o. Revise listing 13.27 of part A of appendix 1.

p. Revise paragraph I of section 113.00 of part B of appendix 1.

q. Amend paragraph K of section 113.00 of part B of appendix 1 by revising 113.00K1a and the third sentence of 113.00K2a, redesignating current 113.00K4 and 113.00K5 as 113.00K5 and 113.00K6, respectively, adding new 113.00K4, and revising newly designated 113.00K5.

r. Revise listing 113.13 of part B of appendix 1.

The revised text is set forth as follows:

APPENDIX 1 TO SUBPART P OF PART 404—LISTING OF IMPAIRMENTS

* * * * *

14. Malignant Neoplastic Diseases (13.00 and 113.00): (Insert date 8 years from the effective date of the final rules.)

* * * * *

Part A

* * * * *

13.00 MALIGNANT NEOPLASTIC DISEASES

* * * * *

I. *What do these terms in the listings mean?*

1. *Inoperable:* Surgery is thought to be of no therapeutic value or the surgery cannot be performed. Examples of when surgery cannot be performed include a tumor that is too large or that invades crucial structures, or you cannot tolerate the anesthesia or surgery due to another impairment(s). This term does not include situations in which the tumor could have been surgically removed but another method of treatment was chosen; for example, an attempt at organ preservation. The determination whether a tumor is inoperable may be made before or after the administration of neoadjuvant therapy. Neoadjuvant therapy is antineoplastic therapy, such as chemotherapy or radiation, given before surgery in order to reduce the size of the tumor.

2. *Metastases:* The spread of tumor cells by blood, lymph, or other body fluid. This term does not include the spread of tumor cells by direct extension of the tumor to other tissue or organs.

3. *Persistent:* Failure to achieve a complete remission.

4. *Progressive:* The malignancy became more extensive after treatment.

5. *Recurrent, relapse:* A malignancy that had been in complete remission or entirely removed by surgery has returned.

6. *Unresectable:* The operation was performed, but the malignant tumor was not removed. This term includes situations in which a tumor is incompletely resected or the surgical margins are positive. This term does not include situations in which a tumor is completely resected but adjuvant therapy is being administered. Adjuvant therapy is antineoplastic therapy, such as chemotherapy or radiation, given after surgery in order to eliminate any remaining cancer cells and lessen the chance of recurrence.

* * * * *

K. *How do we evaluate specific malignant neoplastic diseases?*

1. *Lymphoma.*

a. Many indolent (non-aggressive) lymphomas are controlled by well-tolerated treatment modalities, although they may produce intermittent symptoms and signs. Therefore, we may defer adjudication of these cases for an appropriate period after initiation of therapy to determine whether the therapy will achieve its intended effect. (See 13.00E3.) For indolent lymphoma, the intended effect of therapy is usually stability of the disease process. When stability has been achieved, we will assess severity on the basis of the extent of involvement of other organ systems and residuals from therapy.

b. A change in therapy for indolent lymphomas is usually an indicator that the therapy is not achieving its intended effect. However, it does not indicate this if the change is based on your (or your physician's) choice rather than a failure to achieve stability. If the therapy is changed solely due to choice, the requirements of listing 13.05A2 are not met.

* * * * *

2. *Leukemia.*

a. *Acute leukemia.* * * * Recurrent disease must be documented by peripheral blood, bone marrow, or cerebrospinal fluid examination, or by testicular biopsy. * * *

* * * * *

6. *Brain tumors.* We use the criteria in 13.13 to evaluate malignant brain tumors. We consider a brain tumor to be malignant if it is classified as grade II or higher under the World Health Organization's (WHO's) classification of tumors of the central nervous system (*WHO Classification of Tumours of the Central Nervous System,* 2007). We evaluate any complications of malignant brain tumors, such as resultant neurological or psychological impairments, under the criteria for the affected body system. We evaluate benign brain tumors under 11.05.

* * * * *

13.01 Category of Impairments, Malignant Neoplastic Diseases

13.02 *Soft tissue tumors of the head and neck* (except salivary glands—13.08—and thyroid gland—13.09).

* * * * *

C. Recurrent disease following initial antineoplastic therapy, except recurrence in the true vocal cord.

* * * * *

13.03 *Skin.*

* * * * *

OR

B. Melanoma, as described in 1 or 2.

* * * * *

2. With metastases as described in a, b, or c:

a. Metastases to one or more clinically apparent nodes; that is, nodes that are detected by imaging studies (excluding lymphoscintigraphy) or by clinical examination.

b. If the nodes are not clinically apparent, with metastases to four or more nodes.

c. With metastases to adjacent skin (satellite lesions) or distant sites.

* * * * *

13.05 *Lymphoma* (excluding T-cell lymphoblastic lymphoma—13.06). (See 13.00K1 and 13.00K2c.)

A. Non-Hodgkin's lymphoma, as described in 1 or 2:

1. Aggressive lymphoma (including diffuse large B-cell lymphoma) persistent or recurrent following initial antineoplastic therapy.

2. Indolent lymphoma (including mycosis fungoides and follicular small cleaved cell) requiring initiation of more than one antineoplastic treatment regimen within a consecutive 12-month period. Consider under a disability from at least the date of initiation of the treatment regimen that failed within 12 months.

* * * * *

13.09 *Thyroid gland.*

* * * * *

OR

C. Medullary carcinoma with metastases beyond the regional lymph nodes.

13.10 *Breast.* (except sarcoma—13.04). (See 13.00K4.)

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B. Carcinoma with metastases to the supraclavicular or infraclavicular nodes, to 10 or more axillary nodes, or with distant metastases.

* * * * *

13.11 *Skeletal system*—sarcoma.

* * * * *

13.13 *Nervous system.* (See 13.00K6.)

A. Central nervous system malignant neoplasms (brain and spinal cord), as described in 1 or 2:

1. Highly malignant tumors, such as medulloblastoma or other primitive neuroectodermal tumors (PNETs) with documented metastases, grades III and IV astrocytomas, glioblastoma multiforme, ependymoblastoma, diffuse intrinsic brain stem gliomas, or primary sarcomas.

2. Progressive or recurrent following initial antineoplastic therapy.

* * * * *

13.14 *Lungs.*

* * * * *

OR

C. Carcinoma of the superior sulcus (including Pancoast tumors) with multimodal antineoplastic therapy. Consider under a disability until at least 18 months from the date of diagnosis. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

* * * * *

13.23 *Cancers of the female genital tract*—carcinoma or sarcoma.

* * * * *

E. Ovaries, as described in 1 or 2:

1. All tumors except germ cell tumors, with at least one of the following:

a. Tumor extension beyond the pelvis; for example, tumor implants on peritoneal, omental, or bowel surfaces.

b. Metastases to or beyond the regional lymph nodes.

c. Recurrent following initial antineoplastic therapy.

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13.24 *Prostate gland*—carcinoma.

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B. With visceral metastases (metastases to internal organs).

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13.27 *Primary site unknown after appropriate search for primary*—metastatic carcinoma or sarcoma, except for squamous cell carcinoma confined to the neck nodes.

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Part B

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113.00 MALIGNANT NEOPLASTIC DISEASES

* * * * *

I. *What do these terms in the listings mean?*

1. *Metastases:* The spread of tumor cells by blood, lymph, or other body fluid. This term does not include the spread of tumor cells by direct extension of the tumor to other tissue or organs.

2. *Persistent:* Failure to achieve a complete remission.

3. *Progressive:* The malignancy became more extensive after treatment.

4. *Recurrent, relapse:* A malignancy that had been in complete remission or entirely removed by surgery has returned.

* * * * *

K. *How do we evaluate specific malignant neoplastic diseases?*

1. *Lymphoma.*

a. We provide criteria for evaluating aggressive lymphomas that have not responded to antineoplastic therapy in 113.05. Indolent lymphomas are rare in children. We will evaluate indolent lymphomas in children under 13.05 in part A.

* * * * *

2. *Leukemia.*

a. *Acute leukemia.* * * * Recurrent disease must be documented by peripheral blood, bone marrow, or cerebrospinal fluid examination, or by testicular biopsy. * * *

* * * * *

4. *Thyroid tumors.* We use the criteria in 113.09 to evaluate anaplastic carcinoma and carcinoma treated with radioactive iodine. Medullary carcinoma of the thyroid gland, which is not treated with radioactive iodine, is rare in children. We evaluate medullary carcinoma in children under 13.09C in part A.

5. *Brain tumors.* We use the criteria in 113.13 to evaluate malignant brain tumors. We consider a brain tumor to be malignant if it is classified as grade II or higher under the World Health Organization's classification of tumors of the central nervous system (*WHO Classification of Tumours of the Central Nervous System,* 2007). We evaluate any complications of malignant brain tumors, such as resultant neurological or psychological impairments, under the criteria for the affected body system. We evaluate benign brain tumors under 111.05.

* * * * *

113.01 Category of Impairments, Malignant Neoplastic Diseases

* * * * *

113.13 *Brain tumors.* (See 113.00K5.) Highly malignant tumors, such as medulloblastoma or other primitive neuroectodermal tumors (PNETs) with documented metastases, grades III and IV astrocytomas, glioblastoma multiforme, ependymoblastoma, diffuse intrinsic brain stem gliomas, or primary sarcomas.

* * * * *

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 872

[Docket No. FDA–2008–N–0163] (formerly Docket No. 2001N–0067)

Dental Devices: Classification of Encapsulated Amalgam Alloy and Dental Mercury and Reclassification of Dental Mercury; Issuance of Special Controls for Amalgam Alloy; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening for 90 days, the comment period for the proposed rule, published in the **Federal Register** of February 20, 2002 (67 FR 7620), on the classification of encapsulated amalgam alloy and dental mercury, the reclassification of dental mercury, and the issuance of special controls for amalgam alloy. In the **Federal Register** of July 17, 2002 (67 FR 46941), the initial comment period was reopened for 60 days. The agency is taking this action to provide the public with an additional opportunity to comment and to request data and information that may have become available since publication of the proposed rule.

DATES: Submit written or electronic comments by July 28, 2008.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2008–N–0163 (formerly Docket No. 2001N–0067), by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal, as described previously, in the **ADDRESSES** portion of this document under *Electronic Submissions*.

Instructions: All submissions received must include the agency name and Docket No(s). and Regulatory Information Number (RIN) (if a RIN number has been assigned) for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov*, including any personal information provided. For additional information on submitting comments, see the ''How to Submit Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts