ruleforum.llnl.gov). For information about the interactive rulemaking Web site, contact Ms. Carol Gallagher (301) 415–6219, e-mail: *CAG@nrc.gov.*

FOR FURTHER INFORMATION CONTACT: Brian J. Richter, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone (301) 415–1978, e-mail: *bjr@nrc.gov.*

SUPPLEMENTARY INFORMATION: On November 20, 2003 (68 FR 65386), the NRC published a direct final rule amending its regulations in 10 CFR part 50 related to decommissioning trust fund provisions to correct typographical errors and make minor changes to a final rule entitled ''Decommissioning Trust Provisions,'' promulgated by the NRC on December 24, 2002 (67 FR 78332). In the direct final rule, NRC stated that if no significant adverse comments were received, the direct final rule would become effective on December 24, 2003. The NRC did not receive any comments on the direct final rule. Therefore, this rule is effective as scheduled.

Dated at Rockville, Maryland, this 29th day of January, 2004.

For the Nuclear Regulatory Commission.

Michael T. Lesar,

Chief, Rules and Directives Branch, Division of Administrative Services, Office of Administration.

[FR Doc. 04–2240 Filed 2–3–04; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Parts 2, 4, 5, 9, 16, 375, and 385

[Docket No. RM02–16–001; Order No. 2002–A]

Hydroelectric Licensing Under the Federal Power Act; Order on Rehearing of Final Rule

Issued January 23, 2004.

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Order on rehearing of final rule.

SUMMARY: On July 23, 2003, the Commission issued a final rule amending its regulations to establish a new hydroelectric licensing process that integrates pre-filing consultation with preparation of the Commission's NEPA document and improves coordination of the licensing process with other Federal and state regulatory processes. The final rule retained the existing traditional licensing process and the alternative licensing procedures, and established rule for selection of a licensing process. The final rule also modified some aspects of the traditional licensing process.

The Commission herein denies the requests for rehearing and grants certain requests for clarification.

EFFECTIVE DATE: The revisions implemented in this order on rehearing of the final rule are effective October 23, 2003.

FOR FURTHER INFORMATION CONTACT: John Clements, Office of the General Counsel, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, 202–502–8070.

SUPPLEMENTARY INFORMATION: Before Commissioners: Pat Wood, III, Chairman; Nora Mead Brownell, Joseph T. Kelliher, and Suedeen G. Kelly.

I. Introduction

1. In this order, the Commission addresses requests for rehearing of Order No. 2002, which amends the Commission's regulations for licensing of hydroelectric projects by establishing a new licensing process (the integrated process).[1] The final rule also retains the existing traditional licensing process [2] and the alternative licensing procedures (ALP).[3] Requests for rehearing were filed by the Hydropower Reform Coalition (HRC), Edison Electric Institute (EEI), and Western Urban Water Coalition (WUWC).[4]

II. Discussion

A. Good Cause To Approve Use of Traditional Process

2. The final rule provides that after a transition period ending July 22, 2005, the integrated process will be the default licensing process, but a potential license applicant may apply for authorization to use the traditional process or ALP.[5] The standard for granting a request to use the traditional process or ALP is ''good cause shown.''[6]

3. Potential applicants requesting to use the traditional process and commenters thereon are encouraged to address various criteria. These are: (1) Likelihood of timely license issuance; (2) complexity of the resource issues; (3) level of anticipated controversy; (4) relative cost of the traditional process compared to the integrated process; (5) the amount of available information and potential for significant disputes over studies; and (6) other factors believed by the requester or commenter to be pertinent.[7]

4. HRC states that it supports these criteria, but that the ''good cause'' standard should be specifically linked to overcoming the presumption that the integrated process is the default. Otherwise, it fears, the meaning of ''good cause'' and the significance of the criteria will be ambiguous. HRC requests that we define good cause to mean that use of the traditional process is more likely than the integrated process to maximize coordination of all pertinent regulatory processes, assure timely adoption and implementation of a study plan, and prevent, resolve, or narrow disputes related to the study plan and environmental protection measures.[8]

5. EEI, supported by WUWC, requests that we clarify that good cause may be shown notwithstanding that a licensing proceeding is likely to be complex and controversial. In support, EEI suggests that non-licensees will attempt to thwart requests to use the traditional process by manufacturing issues and controversies. It also reiterates comments on the notice of proposed rulemaking [9] that complexity and controversy may make the integrated process less suitable than the traditional process because the former is more collaborative in nature, and that the cost of the integrated process may be so great as to outweigh all other considerations.

6. We are not persuaded that the regulations need to be changed or clarified in this regard. The outcomes included in HRC's suggested definition may weigh in favor of a good cause finding, but we are not prepared in advance of any requests being filed to conclude that they are the only, or the most important, considerations in all possible cases. We agree with EEI that good cause may be shown notwithstanding that a license proceeding is likely to be complex or controversial, but are also not prepared to speculate on the particular

[1] 68 FR 51070 (Aug. 25, 2003); III FERC Stats. & Regs. ¶ 31,150 (July 23, 2003). Corrections to the final rule were published in the **Federal Register** at 68 FR 61742–61743 (Oct. 30, 2003), 68 FR 63194 (Nov. 7, 2003), and 68 FR 69957 (Dec. 16, 2003). The integrated process regulations are found in 18 CFR part 5.

[2] The traditional licensing process regulations are found in 18 CFR parts 4 and, for relicensing, part 16.

[3] The alternative licensing procedures are found at 18 CFR 4.34(e).

[4] WUWC is composed of various urban water utilities in several western states.

[5] Until July 22, 2005, a potential applicant may elect to use either the traditional or integrated process, but must, as now, receive authorization to use the ALP.

[6] 18 CFR 5.3.

[7] 18 CFR 5.3(c)(1)(ii).

[8] HRC Request at pp. 4–5.

[9] 68 FR 13988 (Mar. 21, 2003); IV FERC Stats. & Regs. ¶ 32,568 (Feb. 20, 2003).

circumstances of future applications in which that would be the case.

B. Pre-Application Document

7. The first step in the integrated process is the potential applicant's notification of intent (NOI) to file a license application and the filing and distribution of the Pre-Application Document (PAD).[10] The PAD is a tool for identifying issues and information needs, including for scoping under the National Environmental Policy Act (NEPA),[11] developing study requests and study plans, and providing information for the Commission's NEPA document. It is a precursor to the environmental exhibit of the license application. It should include all engineering, economic, and environmental information relevant to licensing the project that is reasonably available when the NOI is filed and can be obtained with the exercise of due diligence.

8. Because the PAD plays an essential role in the integrated process, HRC requests that we incorporate into the regulations disincentives for filing and distributing a deficient PAD. Specifically, HRC recommends that a PAD be defined as deficient if the potential applicant fails to properly summarize existing information; show reasonable cause for any content deficiencies; or exercise due diligence in obtaining and presenting existing, relevant materials. Sanctions for a deficient PAD would include: Forfeiture of the potential applicant's right to contest additional information requests (AIRs), a reduced license term, or imposition of preliminary environmental protection measures during the term of annual licenses that may be issued.

9. We decline to adopt this recommendation. HRC's proposed definition largely restates the due diligence requirement that is already in the regulations.[12] Its proposed sanctions miss the mark. There is no incentive to prepare a poor quality PAD, as that would only result in additional data gathering or study requirements in the Commission-approved study plan. In any event, the process leading to the study plan should cure any such deficiencies, which makes the matter of post-application AIRs irrelevant. Forfeiture of a potential applicant's opportunity to contest an AIR would simply impair the Commission's ability to evaluate the merits of the request. Reducing the license term and imposing interim environmental measures are also not relevant to the curing of any deficiencies. As a general matter moreover, we are disinclined to establish a regime of sanctions before we have gained experience in the practical implementation of this new requirement.[13]

C. Dispute Resolution Panel

10. The final rule establishes a formal study dispute resolution process in which resource agencies or Indian tribes with mandatory conditioning authority may dispute any element of the Commission-approved study plan that pertains to the exercise of its conditioning authority. This dispute is submitted to an advisory panel of technical experts. The advisory panel convenes a technical conference before it makes its recommendation, which any interested party may attend, and at which the panel receives additional information and arguments in its discretion before it makes a recommendation based on the record to the Director of the Office of Energy Projects. The Director then resolves the dispute.[14]

11. In recognition of the fact that the potential applicant bears the burden of conducting any studies required in the approved study plan, we afforded it the right to submit comments and information to the advisory panel. This occurs prior to the technical conference.[15]

12. HRC argues that it is unfair and unlawful to grant a potential license applicant this right while other interested entities that are not parties to the dispute may only make submissions if requested to do so by the panel. HRC states that the only apparent reason for the policy is to reduce the process burden, which it contends is not a logical reason for the distinction between potential applicants and others. It adds that the policy will bias the Director's decision in favor of the potential license applicant. In support, HRC notes that the Administrative Procedures Act (APA) generally requires that all interested parties must be given an opportunity to submit facts and arguments,[16] and that the courts have held that the APA should be construed expansively so that the record does not reflect only the views of the project proponent. HRC therefore recommends that we modify Section 5.14(i) to permit any interested party to make a written filing regarding a formal dispute.

13. We decline to make the requested modification. The formal dispute resolution process applies only to disputes between the Commission staff and agencies or Indian tribes with mandatory conditioning authority that relate to the impact of the study plan on the ability of those entities to exercise their statutory authorities. Although other participants in the process may be interested in the outcome of that dispute, the potential applicant clearly has much more at stake because they bear the expense of implementing the study plan. These other participants also do not have the burden that conditioning agencies have to support a condition with substantial evidence.[17]

14. We disagree as well with HRC's suggestion that the formal dispute resolution process excludes other interested entities from making submissions with respect to matters in dispute. The formal process applicable to disputes filed by conditioning agencies occurs only after all entities with an interest in the potential application have had the opportunity to submit information and arguments in support of their study requests during the development of the Commission-approved study plan, which includes meetings for the specific purpose of resolving differences. Any disputes that parties without conditioning authority have with the potential applicant are resolved in that context. As noted, these other parties enjoy an additional opportunity to participate in the technical conference during any formal dispute resolution process that may be initiated with respect to their issues by an entity with mandatory conditioning authority. We anticipate that members of dispute resolution panels will act reasonably when deciding how such participation should be structured.

15. As to assertions of a biased record, the advisory panel will have before it the submissions of the disputing agency and the potential applicant, plus all other information filed during the proceeding. Under these circumstances, we are confident that the panel will

[10] *See* 18 CFR 5.5 and 5.6.

[11] 42 U.S.C. 4321, *et seq.*

[12] 18 CFR 5.6(b)(1)(ii).

[13] HRC also points out that the PAD is required to be distributed to, among others, local governments (18 CFR 5.6(a)(1), but the NOI is not (18 CFR 5.5(c)). Since these documents are to be distributed together, HRC recommends that the distribution lists be reconciled. We agree, and the correction has been made (*see* n.1).

[14] 18 CFR 5.14.

[15] 18 CFR 5.14(j).

[16] HRC cites APA section 554(c), 5 U.S.C. 554(c), which states that agencies must ''give all interested parties an opportunity for the submission and consideration of facts, arguments, offers of settlement, or proposals of amendments when time, the nature of the proceeding and the public interest permit.''

[17] This is fully consistent with APA section 554(c)'s language stating that the manner in which parties can participate can be defined in light of the nature of the proceeding and time constraints.

have all of the information needed to make an unbiased recommendation.

D. Finality of Study Plan Orders

16. EEI contends that study plan orders are final Commission orders binding on potential license applicants and are therefore subject to immediate rehearing and judicial review. EEI adds that study plan orders are inequitable because they are not binding on other parties, apparently in the sense that other parties can make subsequent requests to modify the required studies or make additional information gathering and study plan requests,[18] or may require additional information in the context of their exercise of independent statutory authority, such as acting on applications for water quality certification under section 401 of the Clean Water Act (CWA).[19] EEI states that the Commission should make explicit provisions for rehearing and judicial review of study plan orders or, preferably, modify the rule by making study plan orders advisory.

17. Study plans are not advisory, and EEI's request to consider them as such is denied. As to EEI's other arguments, once the Director makes a study plan determination pursuant to the authority delegated to the Director by the Commission in newly adopted section 375.308(a)(i),[20] that determination may then be appealed to the Commission in a request for rehearing pursuant to section 375.301(a) and 385.713 of the Commission's regulations.[21] Any such occurrence should however be exceedingly rare. The study plan development process was designed to ensure that study requests are subject to established standards, that parties work together to resolve differing opinions, and that the Director's order establishing the study plan rests on the standards and the complete record developed by the participants with the advice and assistance of Commission staff. Whether judicial review of the Commission's decision on rehearing is appropriate is a matter to be determined by the court from which judicial review is sought.

E. Additional Information Requests

18. The rule makes no express provision for parties to make additional information requests following the filing of a license application. Rather, it concludes that the multiple opportunities to request information and studies and to resolve study disputes during the pre-application phase of the proceeding will ensure that the application will include all information needs.[22]

19. HRC states that as a result the last opportunity for new information requests will be in response to the preliminary license proposal (or draft license application, should the potential applicant elect to file one), but that there could be significant changes between the preliminary license proposal and the filed application that would require additional information. This is possible, but unlikely. In any event, and as we previously explained, the possibility of material changes in circumstances has always been inherent in the license application process, and the Commission has always exercised its authority to require additional information in appropriate cases, on its own initiative or in response to the request of a party.[23]

20. Section 5.15(f)[24] provides that requests for new information gathering or studies in response to a potential applicant's updated study report describing its overall progress in implementing the study plan and schedule must demonstrate ''extraordinary circumstances.'' HRC states that this term, which is not defined in the regulations, should be defined as ''factors that could not have been predicted or foreseen under the circumstances, especially those where there is a change in regulation or law.'' [25]

21. We agree in general that unforeseeable events, including changes in laws or regulations, may constitute extraordinary circumstances with respect to identifying information needed for an analysis of a license application. We do not however wish to limit our discretion in this regard to the occurrence of such events, and the mere fact that an event was not foreseeable does not establish a connection between it and a request for additional information. We expect requesters to fully explain the circumstances supporting their requests, and will act reasonably when we consider them.

F. Draft NEPA Documents

22. The Commission sometimes issues in non-controversial cases an environmental assessment (EA) that is not preceded by a draft EA. The integrated process regulations reflect that fact by establishing slightly different procedures depending on whether or not a draft EA is needed.[26] HRC does not state that this practice is unlawful, but suggests that it is generally inconsistent with the thrust of NEPA and the Council on Environmental Quality's (CEQ) regulations, as well as our commitment to attach draft license articles to environmental documents by reducing the parties' opportunities for review and comment. HRC adds that the opportunity to comment on draft EAs can result in changes and corrections that reduce or eliminate requests for rehearing. HRC concludes that a draft EA should be omitted, if ever, only in the most benign of cases. It recommends that we eliminate sections 5.24 and 5.25, and instead include a section which defines limited circumstances under which a draft EA will not be required, based on a list of factors found in CEQ's regulations pertaining to whether or not a proposed action requires an EIS.

23. There is no need to make the changes recommended by HRC. The Commission has exercised its discretion in this regard very conservatively and the integrated process will enhance the parties' opportunities for input on and review of the record upon which the Commission makes its decisions. Sections 5.24 and 5.25 are moreover purely procedural provisions that set forth steps in the integrated process. They have no bearing on the decision of whether or not a draft EA is required.

G. Other Matters

1. Production and Distribution of the PAD

24. HRC believes there may be an inconsistency between the document availability requirements of section 5.2(a) and the PAD distribution requirements of section 5.6. Section 5.2(a) states that a potential applicant must make the PAD and any materials referenced therein available for public inspection at its principal place of business or other accessible location, and to send the same to any requester at the reasonable cost of reproduction and postage. Federal and State fish and wildlife agencies and Indian tribes are, however, required to be provided with these materials without charge.

25. Section 5.6(a) requires the PAD to be distributed to Federal, State, and interstate resource agencies, Indian

[18] Such requests could be made in response to the potential applicant's initial or updated study reports provided for in section 5.15 or in response to the potential applicant's preliminary licensing proposal, as provided for in section 5.16.

[19] 33 U.S.C. 1341.

[20] 18 CFR 375.308(aa)(i).

[21] 18 CFR 375.301(a) and 385.713.

[22] 68 FERC at p. 51,094, III FERC Stats. & Regs. at pp. 30,731–732.

[23] *Id.*

[24] 18 CFR 5.15(f).

[25] HRC Request at p. 19.

[26] *See* 18 CFR 5.24 (applications not requiring a draft NEPA document) and 5.25 (applications requiring a draft NEPA document).

tribes, local governments, and members of the public likely to be interested in the proceeding. Section 5.6(c)(2) provides that sources of information referenced by, rather than included in, the PAD, such as scientific studies and voluminous data, must be provided upon request to recipients of the PAD. HRC is uncertain why the requirements of these sections are not identical, and requests that we clarify that both the PAD and materials referenced therein are available to all recipients of the PAD at no charge.

26. We are granting the requested clarification. The document availability requirements of section 5.2(a) reflect the requirement of FPA section 15(b)(2) [27] that a potential new license applicant maintain a ''library'' of relicensing materials which interested entities may examine and from which they may request documents to be reproduced at cost. It also reflects in part our previously existing requirement that the materials from the library be provided to certain Federal and State agencies at no charge.[28]

27. The PAD contents are related to the relicensing library contents, but are not identical. The PAD and materials referenced therein are to be distributed at no charge to the recipient, as is ordinarily the case with any other document required to be filed with the Commission or served upon other entities. This is consistent with our discussion of the industry's cost concerns in the final rule, wherein we reduced the content requirements for the PAD by permitting supporting materials to be referenced, and encourage potential applicants to take advantage of technological advances by arranging for distribution over the Internet, through CD–ROMs, or by other electronic means.[29] To the extent a potential license applicant elects to include in its relicensing library any materials not required to be included in or referenced in the PAD (or otherwise required to be served on the parties), the potential applicant may charge entities other than Federal and State fish and wildlife agencies and Indian tribes reasonable costs of reproduction and postage.

2. Water Quality Certification

28. The regulations provide that an application to amend a license or an amendment to a pending license application is required to include a new application for a water quality certification if ''the amendment would have a material adverse impact on the water quality in the discharge from the project.'' [30] HRC states that this provision is inconsistent with *Alabama Rivers Alliance* v. *FERC.*[31] The court there interpreted the requirement of CWA section 401(a)(1) [32] that a state water quality certification must be provided or waived for ''any activity'' which ''may result in a discharge'' into navigable waters to include a license amendment which would result in an increase in the discharge from the project turbines. HRC states that we should modify our regulations accordingly. HRC overlooks however the fact that the Court found that the amendment in that case would result in the release of substantially increased volumes of water with low dissolved oxygen levels.[33] We do not interpret the Court's ruling to hold that any increase in a project's discharge, however insignificant and innocuous, requires a new application for water quality certification. The Court moreover noted that the Commission's orders in the case did not address the applicability of the material adverse impact regulation to the licensee's amendment application,[34] and stated that its decision was based solely on its interpretation of the discharge requirement of section 401(a)(1).[35]

3. Cooperating Agencies Policy

29. In the NOPR we proposed to reverse our policy that agencies which have been cooperating agencies for purposes of preparing a NEPA document may not thereafter intervene in a proceeding. In the final rule we concluded that the proposed policy change would violate the prohibitions of the APA and case law against *ex parte* communications.[36]

30. HRC concedes that our analysis in the final rule was correct, but asserts that our rules should include affirmative procedures for coordinating preparation of the Commission's NEPA document with the regulatory processes of other agencies in the absence of a cooperating agency agreement.

31. We conclude that additional regulations are not needed. The integrated process rules provide ample opportunity for such coordination. In fact, the regulations are premised on the active participation of all entities interested in a license application from the time the NOI and PAD are filed. In particular, the integrated process provides for the development with the participation of other agencies a process plan and schedule and a Commission-approved study plan designed to maximize the likelihood that it will produce all the information needed by all agencies with conditioning authority for the proposed project.[37]

4. Timing of Request for Water Quality Certification

32. Some entities have requested clarification of the filing deadline for license applicants to file a request for water quality certification pursuant to CWA section 401. In the integrated, traditional, and alternative processes, effective for applications filed on or after October 23, 2003, the water quality certification application must be filed no later than 60 days following issuance by the Commission of the notice requesting terms and conditions. In the integrated and traditional processes that will also be the notice that the application is ready for environmental analysis.[38] Under the alternative procedures there may not be a specific notice that the application is ready for environmental analysis, but the notice requesting terms and conditions serves the same function.[39]

III. Information Collection Statement

33. The Office of Management and Budget's (OMB) regulations require that OMB approve certain information collection requirements imposed by agency rule.[40] OMB approved the final rule issued in Order No. 2002 on October 28, 2003. No changes have been made to the information collection requirements in this order on rehearing.

IV. Environmental Analysis

34. The Commission is required to prepare an Environmental Assessment or an Environmental Impact Statement for any action that may have a significant adverse effect on the human environment.[41] Included in the

[27] 16 U.S.C. 808(b)(2).

[28] 18 CFR 16.7(e)(3).

[29] 68 FR 51077; III FERC Stats. & Regs. at p. 30,702.

[30] 18 CFR 4.34(b)(5)(iii). Prior to the final rule, this provision was located at 18 CFR 4.38(f)(7).

[31] 325 F.3d 290 (D.C. Cir. 2003).

[32] 33 U.S.C. 1341(a)(1).

[33] 325 F.3d at p. 299.

[34] *Id.* at p. 295, n.6.

[35] *Id.* at p. 296.

[36] 68 FR 51099–51100; III FERC Stats. & Regs. at pp. 30,740–741.

[37] Development of the study plan essentially encompasses all steps from filing and distribution of the NOI and PAD through completion of any needed formal dispute resolution (18 CFR 5.1 through 5.14).

[38] See 18 CFR 4.34(b)(5) (traditional and alternative processes) and 18 CFR 5.23(b) (integrated process). *See also* discussion at 68 FR 51095–51096; III FERC Stats. & Regs. at p. 30,735.

[39] *See* 18 CFR 4.34(b)(5)(ii).

[40] 5 CFR part 1320.

[41] Order No. 486, Regulations Implementing the National Environmental Policy Act, 52 FR 47897 (Dec. 17, 1987), FERC Stats. & Regs., Reg. Preambles 1986–1990 (Dec. 10, 1987).

exclusions are rules that are clarifying, corrective, or procedural or that do not substantively change the effect of the regulations being amended. This rule is clarifying and procedural in nature and therefore falls under the exceptions. Consequently, no environmental consideration is necessary.

V. Regulatory Flexibility Act

35. The Regulatory Flexibility Act of 1980 (RFA) [42] generally requires a description and analysis of final rules that will have significant economic impact on a substantial number of small entities. The Commission is not required to make such an analysis if a rule would not have such an effect. The Commission certifies that this rule does not have such an impact on small entities.

VI. Document Availability

36. 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.

37. From FERC's home page on the Internet, this information is available in eLibrary. The full text of this document is available in 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.

38. User assistance is available for eLibrary and the FERC's website during normal business hours from our Help line at (202) 502–8222 or the Public Reference Room at (202) 502–8371 Press 0, TTY (202) 502–8659. E-Mail the Public Reference Room at *public.referenceroom@ferc.gov.*

VII. Effective Date

39. This order makes no changes to the final rule, which became effective on October 23, 2003. Because no changes were made, the provisions of 5 U.S.C. 801 regarding Congressional review of final rules do not apply to this order.

[42] 5 U.S.C. 601–612.

By the Commission.

Magalie R. Salas,

Secretary.

[FR Doc. 04–2223 Filed 2–3–04; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1271

[Docket No. 97N–484R]

Human Cells, Tissues, and Cellular and Tissue-Based Products; Establishment Registration and Listing; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Interim final rule; correction

SUMMARY: The Food and Drug Administration (FDA) is correcting an interim final rule that published in the **Federal Register** on January 27, 2004 (69 FR 3823). The interim final rule excepted human dura mater and human heart valve allografts, currently subject to application or notification requirements under the Federal Food, Drug, and Cosmetic Act from the scope of the definition of ''human cells, tissues, or cellular or tissue-based products (HCT/P's)'' subject to the registration and listing requirements contained in 21 CFR Part 1271. That definition became effective on January 21, 2004. The interim final rule published with some errors. This document corrects those errors.

FOR FURTHER INFORMATION CONTACT: Paula S. McKeever, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION: In the FR Doc. 04–1733, appearing on page 3824 in the **Federal Register** of Tuesday, January 27, 2004, the following corrections are made:

1. On page 3824, in the **DATES** section, by removing the sentence ''The compliance date is March 29, 2004.''

2. On page 3824, under **SUPPLEMENTARY INFORMATION** in the I. Background section, the phrase ''FDA understands that many establishments may have reasonably expected FDA to delay the effective date of this provision again, since the donor suitability and GTP rules are not yet finalized'' is revised to read:

''FDA understands that many establishments may have reasonably expected FDA to delay the effective date of this provision again, since the donor suitability and GTP rules are not yet finalized. Accordingly, FDA expects that affected firms will be in compliance with these requirements by March 29, 2004, and not on January 21, 2004, the effective date of the definition regulation.''

Dated: January 29, 2004.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 04–2312 Filed 1–30–04; 3:49 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9105]

RIN 1545–BC17

Changes in Computing Depreciation; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correction to final and temporary regulations.

SUMMARY: This document corrects final and temporary regulations (TD 9105) that were published in the **Federal Register** on January 2, 2004 (69 FR 5). The document contains regulations relating to a change in computing depreciation or amortization as well as a change from a nondepreciable or nonamortizable asset to a depreciable or amortizable asset (or vice versa).

DATES: This correction is effective January 2, 2004.

FOR FURTHER INFORMATION CONTACT: Sara Logan, (202) 622–3110 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The final and temporary regulations (TD 9105) that is the subject of this correction is under section 446(e) of the Internal Revenue Code.

Need for Correction

As published, the final and temporary regulations (TD 9105) contain errors that may prove to be misleading and are in need of clarification.

Correction of Publication

Accordingly, the publication of the final and temporary regulations (TD 9105) that was the subject of FR. Doc. 03–31820, are corrected as follows:

1. On page 6, column 1, in the preamble, paragraph 3, line 3, the