

Administration, 1401 Rockville Pike, Rockville, MD 20852, except applicants must send a request for an opportunity to a hearing under § 314.110 on the question of whether there are grounds for denying approval of an application to the Director, Center for Biologics Evaluation and Research (HF-1), at the same address.

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## PART 600—BIOLOGICAL PRODUCTS: GENERAL

21. The authority citation for 21 CFR part 600 continues to read as follows:

**Authority:** 21 U.S.C. 321, 351, 352, 353, 355, 360, 360i, 371, 374; 42 U.S.C. 216, 262, 263, 263a, 264, 300aa-25.

22. Section 600.3 is amended by revising paragraph (jj) to read as follows:

### § 600.3 Definitions.

\* \* \* \* \*

(jj) *Complete response letter* means a written communication to an applicant from FDA usually identifying all of the deficiencies in a biologics license application or supplement that must be satisfactorily addressed before it can be approved.

\* \* \* \* \*

## PART 601—LICENSING

23. The authority for 21 CFR part 601 continues to read as follows:

**Authority:** 15 U.S.C. 1451-1561; 21 U.S.C. 321, 351, 352, 353, 355, 356b, 360, 360c-360f, 360h-360j, 371, 374, 379e, 381; 42 U.S.C. 216, 241, 262, 263, 264; sec 122, Pub. L. 105-115, 111 Stat. 2322 (21 U.S.C. 355 note).

24. Section 601.3 is added to subpart A to read as follows:

### § 601.3 Complete response letter to the applicant.

(a) *Complete response letter.* The Food and Drug Administration will send the biologics license applicant or supplement applicant a complete response letter if the agency determines that it will not approve the biologics license application or supplement in its present form.

(b) *Applicant actions.* After receiving a complete response letter, the biologics license applicant or supplement applicant must take either of the following actions:

(1) *Resubmission.* Resubmit the application or supplement, addressing all deficiencies identified in the complete response letter.

(2) *Withdrawal.* Withdraw the application or supplement. A decision to withdraw the application or supplement is without prejudice to a subsequent submission.

(c) *Failure to take action.* FDA may consider a biologics license applicant or supplement applicant's failure to either resubmit or withdraw the application or supplement within 1 year after receiving a complete response letter to be a request by the applicant to withdraw the application or supplement.

Dated: July 9, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

#### 26 CFR Part 1

[REG-104683-00]

RIN 1545-AX88

### Partial Withdrawal of Proposed Regulations Relating to the Application of Section 904 to Income Subject To Separate Limitations and Computation of Deemed-Paid Credit Under Section 902

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Partial withdrawal of notice of proposed rulemaking.

**SUMMARY:** This document withdraws a portion of a notice of proposed rulemaking published on January 3, 2001, relating to the application of the foreign tax credit limitation under section 904 and the deemed-paid credit under section 902.

**DATES:** The withdrawal of proposed §§ 1.902-0, 1.902-1 and 1.904-4(g) is made on July 20, 2004.

**FOR FURTHER INFORMATION CONTACT:** Bethany A. Ingwalson, (202) 622-3850 (not a toll-free number).

#### SUPPLEMENTARY INFORMATION:

##### Background

On January 3, 2001, the Treasury Department and the IRS published in the **Federal Register** (66 FR 319) a notice of proposed rulemaking (REG-104683-00) providing guidance with respect to the application of sections 902 and 904. Written comments were received and a public hearing on the proposed regulations was held on April 26, 2001. After consideration of the comments received, the Treasury Department and the IRS are withdrawing the portions of the proposed regulations that would have amended §§ 1.902-1 and 1.904-4(g). The amendments to § 1.902-1 would

have terminated the pooling of a foreign corporation's post-1986 undistributed earnings and foreign income taxes if the ownership requirements of section 902(c)(3)(B) were not met as of the end of any taxable year. The amendments to § 1.904-4(g) would have disallowed look-through treatment for a dividend paid by a CFC or noncontrolled section 902 corporation out of E&P accumulated while the corporation was a look-through entity (*i.e.*, the corporation was a CFC or, for tax years beginning after December 31, 2002, a noncontrolled section 902 corporation) if paid after an intervening period during which the corporation was a non-look-through entity (*i.e.*, a less-than-10%-U.S.-owned corporation or, for tax years beginning on or before December 31, 2002, a noncontrolled section 902 corporation).

Final regulations adopting the remaining portions of the proposed regulations are being published in the Rules and Regulations section in this issue of the **Federal Register**. See the preamble to the final regulations for a discussion of the reasons §§ 1.902-1 and 1.904-4(g) are being withdrawn.

#### Drafting Information

The principal author of this withdrawal notice is Bethany A. Ingwalson, Office of Associate Chief Counsel (International). However, other personnel from the Treasury Department and the IRS participated in its development.

#### List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

#### Partial Withdrawal of a Notice of Proposed Rulemaking

Accordingly, under the authority of 26 U.S.C. 7805, §§ 1.902-0, 1.902-1 and 1.904-4(g) of the notice of proposed rulemaking published in the **Federal Register** (66 FR 319) on January 3, 2001 are withdrawn.

**Mark E. Matthews,**

*Deputy Commissioner for Services and Enforcement.*

[FR Doc. 04-16375 Filed 7-19-04; 8:45 am]

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