volume of FDA-approved drugs commercially available in other countries?

• *FDA's Ability to Assure Safety*: What should FDA do to assure safety of imported products? Should FDA examine all imports, or should a sampling method, along with testing, be used to assure safety? What resources would FDA need for different levels of oversight, which could include visual inspection, sampling, and other testing methods to determine quality? Is there a need for, and what is the feasibility of, modifications to the U.S. pharmaceutical distribution system that would help to ensure the safety of drug products imported into the United States under section 1121 of the Prescription Drug, Improvement and Modernization Act of 2003?

• *Regulatory/Legislative Issues*: What, if any, limitations in current legal authorities, such as sections 505, 502, and 801 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355, 352, and 381), may inhibit the Secretary's ability to certify that prescription drugs imported into the United States from Canadian wholesalers or pharmacies are safe? What, if any, limitations in current legal authorities may inhibit the Secretary's ability to certify whether the imported drugs comply with sections 505, 502, and 501 of the act (21 U.S.C. 351) (e.g., Are the drugs approved by FDA?, Do they contain appropriate labeling?, Are they manufactured according to current Good Manufacturing Practice)? If FDA could not assure the same level of safety for imported drugs as consumers expect from drugs purchased at a State-licensed pharmacy, what level of risk would be acceptable?

In what ways would importation of drugs, if permitted under section 1121 of the Medicare Modernization Act, impact U.S. and international intellectual property rights as well as obligations under existing trade agreements? Are there additional legal protections needed for effective enforcement of these rights and agreements?

• *Technology*: What anti-counterfeiting technologies are available and feasible to use to improve the safety of products in the domestic market as well as to prevent the importation of unapproved or counterfeited drug products? What costs would be associated with the implementation of such technologies?

• *Financial Impact*: What would be the short and long term financial impact on drug prices, on drug manufacturers, on pharmacies, on wholesalers, and on patients if section 1121 were to be implemented? What other system costs could be associated with importation of pharmaceuticals from Canada and other countries into the United States?

• *Research and Development*: What would be the impact on research and development of drugs and the associated impact on consumers and patients, if section 1121 of the Prescription Drug, Improvement and Modernization Act of 2003 were to be implemented? Would a reduction in domestic pharmaceutical sales result over time in reduced investment in developing new drugs for the future?

• *Liability Issues*: What, if any, liability concerns would exist for entities in the U.S. pharmaceutical distribution system if importation of drugs from Canada or another country were permitted? If liability concerns do exist, what liability protections do you believe should be implemented?

• *Regulation by Foreign Health Agencies*: What protections do other countries have in place to ensure the safety of drugs that are exported or transshipped from their country to the United States? If these protections are lacking, to what extent are foreign health agencies willing or able to implement new or additional protections to ensure safety of exported or transshipped drugs?

II. Comments

Interested persons should submit to the Division of Dockets Management (see *Registration and Requests for Oral Presentation*) written or electronic comments regarding this document by June 1, 2004. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments received may be reviewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Transcripts

Transcripts of the public meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page or a CD at a cost of $14.25 each.

IV. Electronic Access

Persons with access to the Internet may obtain additional information on the public meeting at *http://www.fda.gov/importeddrugs*.

Dated: March 15, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–6145 Filed 3–16–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG 153172–03]

RIN 1545–BB25

Loss Limitation Rules

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking by cross-reference to temporary regulations.

SUMMARY: In the Rules and Regulations section of this issue of the **Federal Register**, the IRS is issuing temporary regulations under sections 337(d) and 1502 of the Internal Revenue Code relating to the deductibility of losses recognized on dispositions of subsidiary stock by members of a consolidated group, the consequences of treating subsidiary stock as worthless, and when stock of a member of a consolidated group may be treated as worthless. The temporary regulations apply to corporations filing consolidated returns. The text of the temporary regulations published in this issue of the **Federal Register** also serves as the text of these proposed regulations.

DATES: Written or electronic comments must be received by June 16, 2004.

ADDRESSES: Send submissions to: CC:PA:LPD:PR (REG–153172–03), room 5203, Internal Revenue Service, POB 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to CC:PA:LPD:PR (REG–153172–03), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC 20044. Alternatively, taxpayers may submit electronic comments directly to the IRS Internet site at *http:// www.irs.gov/regs.*

FOR FURTHER INFORMATION CONTACT: Regarding the regulations under section 337(d), Mark Weiss (202–622–7790) of the Office of Associate Chief Counsel (Corporate), and regarding the regulations under section 1502, Lola L. Johnson (202–622–7550) of the Office of Associate Chief Counsel (Corporate); regarding submission of comments and/or requests for a hearing, Sonya M.

Cruse (202–622–4693) of the Office of Procedure and Administration (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background and Explanation of Provisions

Temporary regulations in the Rules and Regulations section of this issue of the **Federal Register** amend the Income Tax Regulations (26 CFR part 1) relating to section 337(d) and section 1502. The text of those regulations also serves as the text of these proposed regulations. The preamble to the temporary regulations explains the amendments.

Special Analyses

It has been determined that this notice of proposed rulemaking is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It is hereby certified that these regulations will not have a significant economic impact on a substantial number of small entities. This certification is based on the fact that these regulations will primarily affect affiliated groups of corporations, which tend to be larger businesses. Therefore a Regulatory Flexibility Analysis is not required. Pursuant to section 7805(f) of the Internal Revenue Code, this notice of proposed rulemaking will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Comments and Requests for a Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any written comments (a signed original and eight (8) copies) or electronic comments that are submitted timely to the IRS. The IRS and the Treasury Department request comments on the clarity of the proposed regulations and how they may be made easier to understand. All comments will be available for public inspection and copying. A public hearing may be scheduled if requested by any person who timely submits comments. If a public hearing is scheduled, notice of the date, time and place for the hearing will be published in the **Federal Register**.

Drafting Information

The principal author of the regulations under section 337(d) is Mark Weiss, Office of Associate Chief Counsel (Corporate). The principal author of the regulations under section 1502 is Lola L. Johnson, Office of Associate Chief Counsel (Corporate). However, other personnel from the IRS and Treasury participated in their development.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 1 is amended as follows:

PART 1—INCOME TAXES

Paragraph 1. The authority citation for part 1 continues to read as follows:

Authority: 26 U.S.C. 7805 * * *

Par. 2. Section 1.337(d)–2(c)(2) is added to read as follows:

§ 1.337(d)–2 Loss limitation window period.

[The text of this proposed section is the same as the text of § 1.337(d)–2T published elsewhere in this issue of the **Federal Register**].

Par. 3. Section 1.1502–35(f)(1) is added to read as follows:

§ 1.1502–35 Transfers of subsidiary member stock and deconsolidations of subsidiary members.

[The text of this proposed section is the same as the text of § 1.1502–35T published elsewhere in this issue of the **Federal Register**].

Par. 4. In § 1.1502–80, paragraph (c) is revised to read as follows:

§ 1.1502–80 Applicability of other provisions of law.

(c) [The text of this proposed § 1.1502–80(c) is the same as the text of § 1.1502–80T(c) published elsewhere in this issue of the **Federal Register**].

Mark E. Matthews,

Deputy Commissioner for Services and Enforcement.

[FR Doc. 04–6141 Filed 3–17–04; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[CGD05–03–167]

RIN 1625–AAOO

Safety Zone: Atlantic Intracoastal Waterway, Vicinity of Marine Corps Base Camp Lejeune, NC

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to amend safety zone regulations for the Atlantic Intracoastal Waterway (AICW) and connecting waters, in the vicinity of Marine Corps Base Camp Lejeune, North Carolina. The proposed amendment would provide for additional closures of the AICW of up to 4 hours for Naval weapons training and revise phone numbers for Marine Safety Office Wilmington listed in the regulation. The 4-hour closure periods are necessary to ensure the safety of vessels in this area while facilitating military training and the ammunition certification processes.

DATES: Comments and related material must reach the Coast Guard on or before June 16, 2004.

ADDRESSES: You may mail comments and related material to Commanding Officer, Coast Guard Marine Safety Office, 721 Medical Center Drive Suite 100, Wilmington, NC, 28401. The Port Operations department of Marine Safety Office Wilmington maintains the public docket for this rulemaking. Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, will become part of this docket and will be available for inspection or copying at U.S. Coast Guard Marine Safety Office, 721 Medical Center Drive, Suite 100, Wilmington, NC 28401 between 9 a.m. and 3 p.m. Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: LCDR Charles A. Roskam II, Chief, Port Operations, USCG Marine Safety Office Wilmington, telephone number (910) 772–2207.

SUPPLEMENTARY INFORMATION:

Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related material. If you do so, please include your name and address, identify the docket number for this rulemaking CGD05–03–167, indicate the specific section of this document to which each comment applies, and give the reason for each comment. Please submit all comments and related material in an unbound format, no larger than 8½ by 11 inches, suitable for copying. If you would like to know they reached us, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period. We may change this proposed rule in view of received comments.

Public Meeting

We do not plan to hold a public meeting. But you may submit a request for a meeting by writing to Commanding Officer, Coast Guard Marine Safety Office, 721 Medical Center Drive Suite 100, Wilmington, NC 28401, at the