August 6, 2002

Mr. Jeremy Baskin
Regulations Branch
Office of Regulations and Rulings
U.S. Customs Service
1300 Pennsylvania Avenue, N.W.
Washington, D.C. 20229

Re: Customs Service Notice of Proposed Rulemaking on the Conditional Release Period and Customs Bond Obligations for Food, Drugs, Devices, and Cosmetics (67 Fed. Reg. 39322, June 7, 2002)

Dear Mr. Baskin:

The Office of Advocacy of the U.S. Small Business Administration was created in 1976 to represent the views and interests of small business in Federal policy making activities. The Chief Counsel, who heads the Office of Advocacy, participates in rulemakings when he deems it necessary to ensure proper representation of small business interests. In addition to these responsibilities, the Chief Counsel monitors compliance with the Regulatory Flexibility Act (RFA) and works with Federal agencies to ensure that their rulemakings demonstrate an analysis of the impacts that their decisions will have on small businesses.[1]

The Office of Advocacy would like to provide you with its position concerning the U.S. Customs Service's Notice of Proposed Rulemaking (NPRM) on the Conditional Release Period and Customs Bond Obligations for Food, Drugs, Devices and Cosmetics. The rulemaking seeks to amend current regulations for the importation of goods regulated by the Food and Drug Administration (FDA).

[1] Pub. L. No. 96-354, 94 Stat. 1164 (1981). (codified as amended at 5 U.S.C. §§ 601-612).

Advocacy does not believe that the proposed rulemaking provides an adequate factual basis to support its certification that the rule will not have a significant impact on a substantial number of small entities as is required by the RFA. Further, based on information provided by industry sources, Advocacy is concerned that the rulemaking will prove particularly onerous to thousands of small importers of products regulated by the FDA.

**U.S. Customs' Certification of No Impact is Inadequate**

Section 605(b) of the RFA requires that any agency certifying that a rulemaking will not have a significant impact on a substantial number of small entities must publish in the *Federal Register* providing the factual basis for the certification. The NPRM published in the *Federal Register* on June 7, 2002, provides a certification that the rule will not have a significant impact on a substantial number of small entities. Customs indicates that the certification is based on the fact that, "the proposed regulatory amendments reflect current statutory requirements, and they will not require any additional action on the part of the public but rather are intended to facilitate Customs' enforcement efforts involving existing import requirements." Advocacy believes this statement is vague and that the statement is insufficient under the requirements of the RFA. For example, Customs does not identify any statutory provision that requires it to amend the conditional release period. Therefore, Customs appears to have decided to do so through the regulatory process. As such, Customs is required to comply with notice and comment provisions contained in the RFA and the Administrative Procedure Act (APA).

The most prominent change in current practice contained in the NPRM expands the current 30-day conditional release period to 180-days.[2] Customs does not provide any information in the NPRM as to why the FDA requires a 180-day conditional release period to perform its enforcement functions. Customs' justification for establishing the 180-day conditional release period seems to be derived from the provisions contained in

19 CFR 141.113(b), which prescribes a 180-day conditional release period for purposes of determining the correct country of origin of imported textiles and textile products. Customs should inform the public why the 180-day conditional release period is necessary, and why a lesser period is unreasonable. Also, Customs should consider reasonable alternatives to the rule. This could result in Customs learning that the 180-day conditional release period is unwarranted when balanced against the potential economic injury to small importers of these products.

**The NPRM has the Potential to Affect Thousands of Small Businesses**

The proposed rule has the potential to cost small importers significant revenue. Affected businesses will either have to retain custody of the products for up to six months and incur associated warehousing costs and adverse effects on the commercial value of the product, or distribute the product during the six-month conditional release period and risk liability for penalties that will exceed the value of the imported merchandise. The rule also has the potential to increase the value of customs surety bonds, putting them out of reach for small importers. These dilemmas will likely prove onerous to a small business and will put many import businesses at risk of not surviving.

This is exactly the type of situation that the RFA was designed to ameliorate. Section 603(a - b) of the RFA provides that when an agency cannot certify that a rule will not have a significant impact on a substantial number of small entities, it must prepare an initial regulatory flexibility analysis (IRFA). The IRFA shall describe, *inter alia*, the impact of the proposed rule on small entities, the number of small entities expected to be affected, and a description of applicable alternatives.

[2] In reality, the 180-day conditional release period is 210-days, as the FDA has an additional 30 days beyond the 180-day conditional release period to notify the importer that it has questions about the admissibility of the product.

Advocacy believes that the Customs Service should suspend the NPRM and re-propose the rule to comply with section 603 of the RFA, or reopen the comment period on the current proposal in conjunction with a supplemental IRFA. Thank you for your attention to the above matters. If you have any questions about this correspondence, please do not hesitate to contact Linwood Rayford at (202) 401-6880.

Sincerely,

Thomas M. Sullivan
Chief Counsel for Advocacy

Linwood L. Rayford, III
Assistant Chief Counsel for Advocacy