

JOINT INDUSTRY GROUP

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Regulations Branch
Office of Regulations and Rulings
U.S. Customs Service
1300 Pennsylvania Ave. NW, 3rd Floor
Washington, DC 20229

Dear Sir/Madam:

In a Federal Register Notice of June 7, 2002, Customs requested comments on its proposal to amend the Customs regulations to lengthen the period of time that the Food and Drug Administration (FDA) has to determine whether goods are admissible into the United States. The Joint Industry Group (JIG) submits the following comments in response to this Notice of Proposed Rulemaking.

BACKGROUND

Under the terms of an importer's entry bond, Customs may demand redelivery of merchandise on behalf of another Government agency that determines that the goods fail to comply with applicable laws or regulations governing admission into the United States. (19 C.F.R. 113.62(d)) For example, Customs may release merchandise to the importer subject to confirmation by the FDA that the goods are entitled to admission under the Food, Drug and Cosmetic Act (21 U.S.C. 381). In the event that the FDA later refuses admission, Customs may demand return of the merchandise to its custody. Failure to redeliver the goods normally results in liquidated damages equal to the value of the merchandise, or three times the value of the merchandise for restricted or prohibited merchandise. (19 C.F.R. 113.62(i)(1)). However, in most cases, including FDA violations, "redelivery will be made no later than 30 days after the date that the merchandise was released or 30 days after the end of the conditional release period (whichever is later)." (19 C.F.R. 113.62(d)).

In the Notice of Proposed Rulemaking, Customs proposes to amend its regulations to lengthen the period of time that the FDA has to consider whether the goods are admissible. Under the proposal, the FDA will have a 180-day conditional release period for purposes of rendering a decision. In the event that the FDA refuses to admit the merchandise, Customs has 30 days to issue a notice of redelivery. Therefore, a demand for redelivery could be made up to 210 days from the date the goods were released from Customs custody. In the Notice, Customs explained that the change is to "provide a reasonable period of time to allow the Food and Drug Administration to perform its enforcement functions." Failure to comply with the demand for

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redelivery will result in the assessment of liquidated damages equal to three times the value of the merchandise, or the domestic value of the goods if released under bond.

SUMMARY OF POSITION

The Customs regulations currently strike a balance between the need for the FDA to conduct its investigation and the legitimate need of the trade to dispose of the goods. Today, Customs authority to demand redelivery is limited to 30 days from the date of release, or 30 days from when the importer has notice that the goods have been conditionally released, whichever is later.

Although Customs describes the proposed changes to the regulations as a clarification, in fact they would dramatically extend the time that Customs can demand redelivery for goods subject to FDA regulation. The proposed changes significantly alter the balance of needs in favor of the Government, at the expense of the trade. The changes to the regulations are arbitrary because Customs has not provided any support for its conclusion that 180-days is a reasonable period for the FDA to render a decision on admissibility. Conversely, no account has been taken of the fact that importers cannot reasonably be expected to hold the goods in inventory beyond the period currently specified in the regulations. An importer will rarely be in a position to comply with a demand for redelivery that is issued months after the goods have been released. Under these circumstances, no legitimate government interest is served by requiring the assessment of liquidated damages. Accordingly, we respectfully request withdrawal of the proposed rule.

REDELIVERY UNDER EXISTING REGULATIONS

Section 113.62(d) of the Customs Regulations currently provide that “any demand for redelivery will be made no later than 30 days after the date the merchandise was released or 30 days after the end of the conditional release period.” Under the regulation, a demand for redelivery must be issued within 30 days from the date that the merchandise was released from Customs custody. Alternatively, Customs can demand redelivery within 30 days after the end of the conditional release period.

In United States v. So’s USA Company, Inc., slip op. 99-90 at 5 (CIT August 26, 1999), the Court considered the meaning of the expression “conditional release period.” The Court specifically rejected Customs position that any release before liquidation is conditional. Moreover, it also indicated that an importer must have affirmative notice that goods are released conditionally in order to extend the redelivery period beyond 30 days from the date of release. Accordingly, the period Customs has to demand redelivery for FDA issues is currently fairly circumscribed. Customs now seeks to modify the regulations in order to reverse the result of the Court’s decision.

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THE PROPOSAL TO EXTEND THE CONDITIONAL RELEASE PERIOD IS ARBITRARY

The proposal is not reasonable because the trade cannot hold the merchandise in inventory for 210 days:

In today's economy, merchandise must be disposed of quickly in order to minimize overhead and inventory costs. Components that are used in the production of goods are delivered on a just-in-time basis. Merchandise imported for retail sale is typically sold within 2-4 weeks. Managing the flow of shipments is critical to a company's profitability.

If the FDA does not give explicit notice that the importer may proceed, then the importer must decide whether to hold the goods or to release them for sale or for manufacture. For a short period of time, the importer may be able to hold the goods pending a decision from the FDA. However, this is not an option if the FDA decides to withhold a decision on admissibility for months at a time. This is the case because the failure to timely deliver components can result in production line shutdowns, idling of employees, breach of contracts and loss of sales. Moreover, the failure to release finished goods for sale can result in breach of contracts and loss of sales. In this regard, it should be noted that many technology products are replaced with newer models within 210- days.

The proposal to extend the conditional release period without considering the impact on the trade is not reasonable. As a practical matter, a Notice of Redelivery issued months after entry will automatically result in the assessment of liquidated damages. This may generate Government revenue, but it will not act as a deterrent because companies simply cannot hold goods in inventory for such a long period of time.

The proposal is arbitrary because the Government has not explained the need for a 180-day period to render a decision on admissibility:

In the Notice of Proposed Rulemaking, Customs indicated that the 180-day is "a reasonable period of time to allow the Food and Drug Administration to perform its enforcement functions." Neither Customs nor FDA provided any information that explains why it would take so long to render a decision. At a minimum, the reasons for such a delay should be identified and an attempt should be made to address such concerns in a less intrusive manner.

The FDA has an obligation to render a decision on admissibility within a reasonable period of time. The measure of what is reasonable should take into account not only the needs of the Government, but also the commercial realities of trade. In our view, the Government should identify products for sampling and perform any necessary testing contemporaneous with

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shipment arrival. The time periods laid out in the current regulations are more than adequate for these purposes.

Instead of imposing unrealistic burdens on trade, the Government should be looking at ways to improve its ability to screen imported goods. Since the trade will be transmitting manifest information to Customs in advance of shipment arrival, the FDA should be looking at ways of sharing this information for purposes of pre-screening. Risk management techniques should be employed to identify high-risk shipments for inspection. Adequate resources must be secured to ensure that there are enough inspectors, and that automated systems may be used to identify goods for examination. Ultimately, these are far more effective means of performing health and safety evaluations than attempting to recall goods that have already been released from custody.

CONCLUSION

For reasons set forth above, we respectfully request withdrawal of the Notice of Proposed Rulemaking concerning redelivery of goods for FDA purposes.

Regards,



Ronald Schoof
Chairman
Joint Industry Group