



C O N S U L T I N G G R O U P

1704 '00 DEC 21 P1:58

December 20, 2000

Food and Drug Administration
Dockets Management Branch (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20857

Re: **AAC Consulting Group, Inc. Comments to Docket No. OOD-1601**
"Guidance for Industry and for FDA Employees on Import Alert #66-66"
(Published December 4, 2000, 65 Fed. Reg. 75718)

AAC Consulting Group, Inc., Rockville, Maryland represents domestic and foreign API drug manufacturers and importers. AAC is supportive of the Food and Drug Administration's efforts to insure that only approved Active Pharmaceutical Ingredients (APIs) are permitted importation into the United States. To this end we encourage our clients to fully comply with all FDA laws and regulations as they apply to manufacturing, packaging, labeling, exporting and importing of their APIs.

STATEMENT OF FACTS

In the past, the normal procedure for FDA was to have had either a violative sample that met agency criteria for a single violation or multiple sample violations to place the foreign supplier and product on an import alert. In addition, FDA may conduct a foreign inspection of a facility to determine compliance with U.S. laws and regulations. If the inspection determined the manufacturer was not in compliance with GMPs or QMS standards, a letter would be sent to the identified manufacturer advising them they should not ship their product to the US because it would be detained. Also, under "Other Situations: in cases other than those described above, a recommendation may be made for automatic detention if there is a reason to believe, and evidence to support, that future shipments of a product or class of products will appear violative within the scope of Section 801(a)." These procedures are identified in the Agency's Regulatory Procedures Manual (RPM) Chapter 9 Imports, Subchapter "Automatic Detention" a/k/a "Detention without Physical Examination".

OBSERVATION

In the issuance of Import Alert #66-66, ("Detention without Physical Examination of API's That Appear To Be Misbranded Under 502(f)(1) Because They Do Not Meet the Requirements for the Labeling Exemptions in 21 CFR 201.122") it appears FDA has employed a new procedure for determining which foreign manufacturers and products are to be included in the attachment to an alert.

OOD-1601

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BACKGROUND

Entry records are submitted by US Customs House Brokers (filers) who are authorized to submit entry documentation to FDA via an electronic process (Customs Automated Commercial System-ACS and Operational and Administrative System for Import Support-OASIS). However, in this processing of entry data, a chemical that may also be an API, may be entered without appropriate notation that the chemical is intended for research and/or testing. It would therefore appear the article is an API and not appropriate for importation, as identified by the alert.

Since this import alert appears to be based on the review of OASIS records of past importations, it seems the Agency used an arbitrary approach to determining which suppliers/products would be listed in the attachment to the alert. This is further supported by the fact the actual hard copies of the entry documents were not available to the Center and the office reviewing the OASIS records.

Another concern for importers of APIs is the issue of identifying the appropriate NDA, ANDA, etc., for an API that is used by many different holders of approved products. This situation is primarily the concern of bulk drug brokers. Many drug brokers will import a particular chemical for their customers in advance of actually receiving orders. Because they are not sure which approved holder of the substance will need the product at any given time, they are faced with the issue of which NDA/ANDA number to provide at the time of importation.

FINDINGS

Based on the aforementioned, it appears some manufacturers and products were included in this alert based on incomplete information. Many of the products identified in the attachment were not intended for use in the manufacture of approved drugs but were intended for use in research, development, and testing. Unless the information regarding a particular chemical was properly identified to the reviewer making the determination of compliance, it may appear a non-authorized importer was entering the article. Since the article was never intended for further manufacturing or processing in the preparation of a finished drug product for use in man or animal it should not have been considered an API covered by this alert. (See IA#66-66, Reason for Alert (OASIS entry records can be compared to CDER records for NDAs, ANDAs, and IND exemptions to verify the source and status of an API.)

Under the current procedure in OASIS, the drug broker is listed as the consignee. The broker will not have an approval number for their own operations, and unless the product is being imported for one particular client, the drug broker will have to provide all possible clients holding approval numbers to FDA to cover all potential customers. This will represent an additional burden on the importers, filers, FDA district reviewers and the Center. We believe additional guidance regarding this situation must be issued to FDA field offices.

In the RPM guidance for "Automatic Detentions" (DWPE), there are procedures listed for how a named firm on an import alert may be removed from the alert. In this situation, none of the

current procedures appear to cover this particular alert. The alert does provide guidance on what a district should consider when evidence is presented for a shipment that is detained under this alert, but the guidance does not provide a suitable procedure for named firms/products to be removed from the alert.

RECOMMENDATIONS

We therefore recommend re-examination of all firms and products included in this alert to assure the identified article was intended for actual drug product, or manufacture for commercial use. Unless such evidence is shown to support the listing under this alert the name of the foreign supplier and product should be deleted.

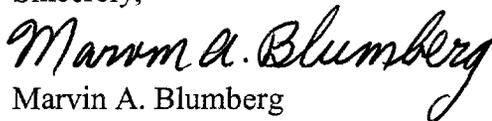
We further recommend an additional section to the guidance portion of the alert to show what will be required to have a firm/product removed from the attachment of the alert. If the foreign manufacturer provides a list of their consignees in the US who will receive the API and their product approval numbers (where applicable); will this be sufficient to remove their name? If they can document the product identified in the attachment was only shipped for research/testing, should this support removal? Where the shipment is consigned to a drug broker and not a specific manufacturer, if the drug broker can provide documentation all product imported (by specific named product or all products covered by the alert, i.e., APIs) are for holders of approvals (where necessary) and that they are legally authorized to import such bulk drugs (via state licenses, etc.) is that sufficient for removal of the foreign supplier?

CONCLUSIONS

We believe this import alert was improperly implemented. The exporting and importing API drug companies have for many years seen little or no real coverage of their importations by FDA. We believe the alert should have been issued either as a Compliance Policy Guide, Guidance Alert, or a Surveillance Alert, but clearly not a Detention without Physical Examination Alert. Only after the proper notification of FDA's change in the policy regarding additional screening coverage of APIs, and then by actual examination of entry records, including labeling where necessary, should the import alert for Detention without Physical Examination have been issued.

AAC Consulting Group, Inc. reserves the right to submit additional comments for itself and as a representative of manufacturers/importers of APIs.

Sincerely,



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