

May 28, 1968

As a temporary measure, pending announcement of final statistics to be issued by the U.S. Tariff Commission on total apparent United States watch consumption during 1967 and the verification of data submitted in support of individual quota applications, initial 1968 calendar year quotas were allocated to eligible producers that received a duty-free watch quota allocation for calendar year 1967.

On March 27, 1968, the 15 applicants producing watches and watch movements in the Virgin Islands to which an initial quota allocation had been made were advised that representatives of the two Departments would be in the Virgin Islands beginning on the week of April 8 to verify the data submitted. The verification which is now completed indicated that firms had been accurate in reporting the number of units which were entered into the customs territory of the United States during calendar year 1967. Inconsistencies, however, occurred in reporting wages subject to FICA taxes paid by some firms during calendar year 1967 which were attributable to watch operations in the Virgin Islands. These inconsistencies were largely due to the inclusion of wages in excess of the maximum \$6,600 taxable as FICA wages and the inclusion of wages paid to individuals whose services were not attributable to watch operations in the Virgin Islands.

Any watches and watch movements entered duty-free into the customs territory of the United States on or after January 1, 1968, are to be deducted from the following allocations which are issued for the full calendar year 1968. Adjustments have been made reflecting verification of the data submitted by individual applicants; however, the quotas announced are subject to possible reduction or revocation in the case of those firms which failed to enter into the customs territory of the United States at least 30 percent of their initial quota on or prior to April 1, 1968. Such firms will be notified in the near future of any action the Departments propose to take based on their failure to meet this requirement. The quota allocated to Virgiline Watch Co., Inc. was made pursuant to a petition for relief on the grounds of extraordinary circumstances, following a transfer of control over the management of the firm approved by the Departments.

VIRGIN ISLANDS

	Name of Firm	Number of Units
1.	Admiral Time Inc.	226,069
2.	Antilles Industries, Inc.	465,003
3.	Atlantic Time Products Corp.	369,592
4.	Belair Time Corp.	257,343
5.	Belmont Industries	110,514
6.	Master Time Co., Ltd.	212,032
7.	Quality Products Co., Inc.	443,247
8.	Roza Watch Corp.	298,532
9.	R. W. Summers Time Corp.	196,992
10.	Standard Time Corp.	686,282
11.	Sussex Watch Corp.	80,851
12.	Unitime Corp.	495,105
13.	Virgiline Watch Co., Inc.	25,000
14.	Virgo Corp.	231,570
15.	Watches, Inc.	110,618

These quotas may be adjusted at any time during this calendar year in the event it becomes apparent that shipments through December 31, 1968, by any firm will be less than 80 percent of the number of units allocated to it. The adjusted quotas for firms located in Guam will be announced in the near future, as soon as the verification of the data submitted by these firms has been accomplished.

LAWRENCE C. MCQUADE,
Assistant Secretary for Domestic and International Business, Department of Commerce.

HARRY R. ANDERSON,
Assistant Secretary for Public Land Management, Department of the Interior.

MAY 23, 1968.

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DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration DRUGS FOR HUMAN USE

Drug Efficacy Study Implementation Announcement Regarding Protamine Sulfate Antihemorrhagic Preparations

The Food and Drug Administration has reviewed and evaluated reports received from the National Academy of Sciences—National Research Council, Drug Efficacy Study Group, on the following protamine-type antihemorrhagic preparations:

1. Protamine sulfate injection; ampoules, 10 milligrams per milliliter; manufactured by Eli Lilly & Co., Indianapolis, Ind. 46206.
2. Desiccated protamine sulfate sterile powder; 50 milligrams per vial; manufactured by The Upjohn Co., Kalamazoo, Mich. 49002.

The Food and Drug Administration concurs in the conclusions of the Academy that these drugs are effective only as antidotes for heparin overdosage.

Supplements are invited to revise the labeling provided for in the new-drug applications covering the above-listed preparations to limit the claims and present the conditions of use substantially as follows:

Actions. Protamines are rich in arginine and are strongly basic; this property accounts for the antihemorrhagic effect. Protamine combines with the strongly acidic heparin to form a stable salt with loss of anticoagulant activity. Protamine itself has an anticoagulant effect.

Indication. Antidote to heparin overdosage.
Precautions. When protamine sulfate is administered, it should be given slowly (in 1 to 3 minutes), intravenously, in doses not exceeding 50 milligrams in any 10-minute period; facilities to treat shock should be available.

Protamine sulfate can be inactivated by blood, and when it is used to neutralize large doses of heparin, a heparin "rebound" may be encountered. This complication is treated by additional protamine injections as needed.

Adverse reactions. Intravenous injections of protamine may cause a sudden fall in blood pressure, bradycardia, dyspnea, or transitory flushing.

Dosage and administration. Protamine sulfate is for intravenous administration only. It should be given intravenously very slowly—no more than 50 milligrams over 10-minute periods. The usual dose is 1.0 to 1.5 milligrams, which has been shown clinically to antagonize 78–95 units of heparin. If administered within 30 minutes after a dose of heparin, only 0.5 milligram of protamine sulfate is required to antagonize each 78–95 units of heparin. (For powder, include instructions for preparation of injection from sterile powder.)

The holders of new-drug applications for the drugs listed above have been mailed a copy of the NAS-NRC report together with a copy of the labeling conditions in this announcement. Any manufacturer, packer, or distributor of a drug of similar composition and labeling to the drugs listed in this announcement or any other interested person may obtain a copy of the NAS-NRC report by writing to Food and Drug Administration Press Relations Office, 200 C Street SW., Washington, D.C. 20204.

The Commissioner of Food and Drugs invites all holders of new-drug applications for the drugs listed, as well as any interested person or persons who may be adversely affected regarding this announcement, to meet informally with officials of the Food and Drug Administration to discuss any medical matters relating to the conclusions and labeling for the subject drugs.

For this purpose a meeting will be held at 10 a.m., in Room 207, Crystal Plaza No. 5, 2211 Jefferson Davis Highway, Arlington, Va., on July 1, 1968.

Persons desiring to attend such meeting should notify the agency in advance by writing to the Special Assistant for Drug Efficacy Study Implementation, Bureau of Medicine, Food and Drug Administration, 200 C Street SW., Washington, D.C. 20204.

Any written comments regarding this announcement may be addressed to the Special Assistant for Drug Efficacy Study Implementation at the above address. Comments concerning medical matters or labeling intended for discussion at the meeting should be received no later than 20 days before the scheduled meeting date.

This notice is issued pursuant to the authority vested in the Secretary of Health, Education, and Welfare by the Federal Food, Drug, and Cosmetic Act (secs. 502, 505, 701(a), 52 Stat. 1050–53, as amended, 1055; 21 U.S.C. 352, 355, 371(a)) and delegated to the Commissioner (21 CFR 2.120).

Dated: May 21, 1968.

JAMES L. GODDARD,
Commissioner of Food and Drugs.

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