As the recipient of the 1971 Samoan watch quota has abided substantially with the terms and conditions of its application, the Departments will not invite applications from new entrants for the allocable calendar year 1972 American Samoa watch quota unless the amount of such quota is sufficiently greater than the available 1971 calendar year quota as to sustain more than one economically viable watch assembly operation in American Samoa. Such information will become available to the Departments on or about April 1, 1972, at which time, in the unlikely event that the quota for calendar year 1972 avers to be substantially greater than for calendar year 1971, the Departments would consider the possibility of inviting applications from new entrants. A decision to issue such an invitation would be published in the FEDERAL REGISTER before June 1, 1972.

SEC. 8. The rules restricting transfers of duty-free quotas issued on January 29, 1968, and published in the FEDERAL REGISTER on January 31, 1968 (33 F.R. 2399), are hereby incorporated by reference as applicable to transfers of quotas issued during calendar year 1972 except that detailed reporting of ownership and control will be reported on an annual basis on Form OIPF-764 at the time the firm applies for an annual duty-free watch quota for calendar year 1972. Subsequent change in ownership and control will be reported on April 15, July 15, and October 15, 1972, on Form OIPF-844 required in section 2 above.

Any interested party has the right to petition for the amendment or repeal of the foregoing rules and may seek relief from the application of any of their provisions upon a showing of good cause under the procedures relating to reviews by the Secretaries of Commerce and the Interior which were published in the FEDERAL REGISTER on November 17, 1967 (32 F.R. 15818).

Dated: January 3, 1972.

HARRISON LOESCH,
Assistant Secretary for Public Land Management, Department of the Interior.

STANLEY NEHMER,
Deputy Assistant Secretary for Resources, Department of Commerce.

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DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

OVER-THE-COUNTER ANTIBACTERIAL INGREDIENTS IN DRUG PRODUCTS FOR REPEATED DAILY HUMAN USE

Request for Data and Information Regarding Safety and Efficacy Review

The FDA is undertaking a review of all over-the-counter (OTC) drug products currently marketed in the United States, to determine that these OTC products are safe and effective for their labeled indications. This review will utilize expert panels working with FDA personnel.

A notice of proposed rule making outlining procedures and explaining the purpose for this review was published in the FEDERAL REGISTER of January 5, 1972.

To facilitate this review and a determination as to whether an OTC drug for human use is generally recognized as safe and effective and not misbranded under its recommended conditions of use, and to provide all interested persons an opportunity to present for the consideration of the reviewing experts the best data and information available to support the stated claims for these drug products that contain antibacterial ingredients, we are inviting submission of data, published and unpublished, and other information pertinent to all active ingredients utilized as antibacterial components of drug products for repeated human use.

FDA is aware that the following active ingredients are used in such products:

Hexachlorophene.
Resorcinol.
Salicylic acid.
Zinc sulfate.
Benzethonium chloride.
Triclocarban (TCC).
Cloflucarban.
Tribromsalan (TBS).

Interested parties are also invited to submit data on any other active antibacterial ingredients which they may wish to be considered.

To be considered, seven copies of the data and/or views must be submitted in the following format:

OTC DRUG REVIEW INFORMATION

I. Label(s) and all labeling.

II. A statement of the complete quantitative composition of the drug.

III. Animal safety data.

A. Individual active components.

1. Controlled studies.

2. Partially controlled or uncontrolled studies.

B. Combinations of the individual active components.

1. Controlled studies.

2. Partially controlled or uncontrolled studies.

C. Finished drug product.

1. Controlled studies.

2. Partially controlled or uncontrolled studies.

IV. Human safety data.

A. Individual active components.

1. Controlled studies.

2. Partially controlled or uncontrolled studies.

3. Documented case reports (not testimonial reports).

4. Pertinent marketing experiences that may influence a determination as to the safety of each individual active component.

B. Combinations of the individual active components.

1. Controlled studies.

2. Partially controlled or uncontrolled studies.

3. Documented case reports (not testimonial reports.)

4. Pertinent marketing experiences that may influence a determination as to the safety of combinations of the individual active components.

C. Finished drug product.

1. Controlled studies.

2. Partially controlled or uncontrolled studies.

3. Documented case reports (not testimonial reports).

4. Pertinent marketing experiences that may influence a determination as to the safety of the finished drug product.

V. Efficacy data.

A. Individual active components.

1. Controlled studies.

2. Partially controlled or uncontrolled studies.

3. Documented case reports (not testimonial reports).

B. Combinations of the individual active components.

1. Controlled studies.

2. Partially controlled or uncontrolled studies.

3. Documented case reports (not testimonial reports).

C. Finished drug product.

1. Controlled studies.

2. Partially controlled or uncontrolled studies.

3. Documented case reports (not testimonial reports).

VI. A summary of the data and views setting forth the medical rationale and purpose (or lack thereof) for the drug and its ingredients and the scientific basis (or lack thereof) for the conclusion that the drug and its ingredients have been proven safe and effective for the intended use. If there is an absence of controlled studies in the material submitted, an explanation as to why such studies are not considered necessary must be included.

Data should be submitted to:

Food and Drug Administration, Bureau of Drugs, OTC Drug Products Evaluation Staff (BD-106), 5600 Fishers Lane, Rockville, Maryland 20852.

These data shall be submitted within 30 days from date of this publication.

(Federal Food, Drug, and Cosmetic Act, sec. 701; 21 U.S.C. 371)

Dated: January 3, 1972.

CHARLES C. EDWARDS,
Commissioner of Food and Drugs.

[FR Doc.72-210 Filed 1-6-72;8:45 am]

Public Health Service

REGIONAL HEALTH DIRECTORS

Delegation of Authority

I hereby delegate to the Regional Health Directors the authority to make grants to units of general local government in any State of their respective regions following the provisions of title I and title II of Public Law 91-695 (42 U.S.C. 4801-4811), the Lead-Based Paint Poisoning Prevention Act.

VERNON E. WILSON, M.D.,
Administrator.

DECEMBER 29, 1971.

[FR Doc.72-244 Filed 1-6-72;8:45 am]