Carson Frailey's WASHINGTON LETTER

DCAT

Bulletin No. 956 January 27, 1964

DRUG INVESTIGATION

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DRUG TESTING

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The Good Manufacturing Practice rules, consequently, apply only to firms making finished dosage form drugs. This point has arisen in connection with the question of the responsibility for testing the components of drugs. FDA says that there is no provision in the Act or regulations which would require the maker of a raw material or a bulk chemical to be used as the component, to furnish to his customer a protocol of analysis of the article shipped. Further, FDA stresses the fact that even if the dosage form firm should receive protocols of analysis from a supplier, the Good Manufacturing Practice regulations would, nevertheless, require the consignee to test the commodity which he receives. FDA cites Regulation 133.6 and 133.11 to make it clear that firms purchasing chemicals in bulk must test these components whether or not they receive protocols of assay from their suppliers.

Regulation 133.6 reads as follows:

> "Components used in the manufacture and processing of drugs, regardless of whether they appear on the finished products, shall be identified, stored, examined, tested, inventoried, handled and otherwise controlled in a manner to assure that they conform to appropriate standards of identity, strength, quality and purity, and are free of contaminants at time of use, and to provide that appropriate records are maintained of their origin, receipt, examination, testing, disposition, and use in drug manufacture or processing."

Regulation 133.11 reads in part as follows:

"Laboratory controls shall include the establishment of adequate specifications and test procedures to assure that components *** conform to appropriate standards of identity, strength, quality, and purity. Laboratory controls shall include: (a) The establishment of master records containing appropriate specifications for each component used in drug production and a description of the test procedures used to check them, including provisionfortesting adequately representative samples. Such records shall also provide for appropriate retesting of materials subject to deterioration."

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Cyanamid is required to license only those applicants intending to use Aureomycin for "making and selling tetracycline", and is not deprived of the right to stop other parties from selling the patented product Aureomycin. FTC further ordered Pfizer, Cyanamid and four other concerns -- Bristol Myers Co. Bristol Laboratories, Inc., Olin Mathieson Chemical Corp. (Squibb), and Upjohn Co.--to stop conspiring to fix prices and submitting rigged bids on tetracycline, and to individually and independently cancel existing prices a redetermine new ones within sixty days.

TETRACYCLINE (Con't.)

CARSON FRAILEY'S WASHINGTON LETTER (Con't.)

Specific provisions of the order are -- (1) Royalties collected by Pfizer and Cyanamid may not exceed 2 1/2 percent of licensees' net sales of tetracycline; (2) an applicant may be required to pay $2,500 upon being issued a license, which amount shall be applied against future royalties. This provision is to preclude "harassment by fly-by-night operators who have no bona fide intent to manufacture and sell tetracycline; (3) Pfizer and Cyanamid must furnish licensees, upon written request, all technical information and know-how relating to the manufacture of chlortetracycline and tetracycline exchanged by the two companies in the past.

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The Air Force says a solid-electrotyle fuel cell concept is feasible. 3-cell units weighing 6 g., occupying 6.2 cu.cm. have been built delivering 2.1 watts operating at electrolyte densities of 750 ma./sq. and at an operating temperature of 1,000° C. Report on request, $2.00

Art. #9 Foreign Notes

(a) Drug Residues - The Canadian Food and Drugs Act is proposed to be amended by the addition of the following section: "No person shall sell a drug recommended for use in animals which may be consumed as food unless the manufacturer thereof has, on request, filed with the Director, in form, manner and content satisfactory to him, a submission, in duplicate, that includes details of tests carried out to demonstrate that no residues of the drug remain in meat, meat by-products, eggs or milk except as provided in these Regulations."

Absence of residues may be achieved either by adjusting the conditions of use of the drug or by terminating its use at a time which will ensure the absence of residues. In either case, the manufacturer should submit information to demonstrate that residues will not be present in edible products at the time they are proposed to be sold. If a withdrawal period is required for drugs to be adminstered to lactating cattle, it must not exceed 96 hours. Since some drugs cannot be used effectively on a "no residue basis", consideration will be given to the establishment of appropriate tolerances.

Detailed reports of tests made to establish the safety of such residues will be required before consideration can be given to their establishment. Comments should be addressed to C. A. Morrell, Director, Food & Drug Directorate, Department of National Health and Welfare, Ottawa, before February 15.

DRAFT

(b) Paint - A relatively small but well established paint maker in Baghdad Iraq, seeks the technical assistance of a U.S. paint manufacturer. The firm wants to improve and expand production which at present runs at the annual rate of $200,000 in terms of local currency.

(c) Acids in Spain - Licensing and financial assistance is sought from a U.S. firm in order to expand present production to include sorbic and terephthalic acids. Name on request.

(d) Urea/Ammonia Plant - American private investments' largest enterprise in Taiwan to date is the $22.5 million urea/ammonia plant which is a joint investment of Socony Mobil, Allied Chemical, China Petroleum Corp. The plant utilizes abundant natural gas in expected annual production of 100,000 tons of urea and 50,000 tons of ammonia.

(e) Baby Feeding - A U.S. licensee is sought to produce and sell a French-developed device for feeding infants or young animals solid or semi-solid foods. The developer of the device, who has applied for U.S. patent, claims that his invention provides a completely new, safe and easy method of infant feeding. Complete drawings and additional information available.

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Art. #10

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REGULATIONS FOR COLOR ADDITIVES

Entire product must be safe

Pre-market proof

Hair dyes

Patch test

FDA may refuse to certify

Many subjects covered

Safety factor

The Food and Drug Administration has published regulations for color additives used in foods, drugs, and cosmetics. The regulations implement the Color Additive Amendments.

1. Additional safety precautions are provided for lipsticks, rouge, eyebrow and lash color and other substances that apply color to the human body. Under the new regulations, FDA will require that an entire product--not just the color ingredient--be shown by the manufacturer to be safe before it is released for sale. Previously only color of the coal tar type ingredients had been subject to the requirement for pre-marketing proof of safety. Commissioner Larrick said the new requirement is based on the language in the law and the legislative intent to insure that the entire formulation of a "color additive" is safe for the consumer.

2. The language of the regulation dealing with exemption of hair dyes from the safety clearance and certification requirement has been clarified to show that the "patch test" requirement applies only to hair dyes which are dangerous because the user may be sensitive to them.

Commissioner Larrick says that the exemption in the 1938 law was conditioned on labeling requirement calling for the use of a patch test to determine whether the user is sensitive to the color before the hair dye is applied. The patch testing requirement offers no protection from other types of toxicity, says Larrick, and the purpose of the new regulation is to close the gap. Hair dyes that do not cause a reaction with the patch test must now be demonstrated to be safe before they can be marketed.

3. The regulations provide that FDA may refuse to certify a color additive --if the manufacturer refuses FDA inspectors access to manufacturing facilities, processes, and formulas involved in manufacture of the additive.

FDA cannot determine whether the conditions for safe use of color additives, including products exempt from certification, are being met unless a complete inspection of the plant and formulas can be made, according to Larrick.

The regulations cover such matters as definition of terms, fees to be charged for listing and certification of batches of colors, labeling requirements for colors, time schedules for acting upon petitions, protection of trade secrets, procedures for obtaining certification, or exemption from certification of batches of both coal tar and non-coal tar colors; and procedures for filing objections and requesting public hearings on regulations.

Safety data which may be required under the regulations include detailed data from appropriate animal and other biological experiments; information as to chemical identity and composition and physical, chemical and biological properties; a description of tests, facilities and controls used in manufacture; data on stability, including a proposed expiration date where necessary; and, when needed, satisfactory methods for detecting and measuring the color in the products in which it would be used.

The regulations provide that a safety factor of 100 to 1 will ordinarily be used in applying animal experimentation data to man, unless use of a different factor is supported by the data submitted; and provide for taking into account any probable additive effect of the toxicity of the color with that of other related colors or with food additives or pesticides which may also be present in foods.

DRUG INVESTIGATION

DRUG TESTING

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