CHAPTER 24 - DEVICES

SUBJECT: Cytotoxic Testing for Allergic Diseases

BACKGROUND:

A number of Federal and state agencies which share responsibility for the regulation or licensure of medical testing laboratories are concerned about allergy clinics, health centers, and testing laboratories performing the cytotoxic test and promoting the test as effective in the detection of allergic diseases, particularly for food and food additives. The Health Care Financing Administration (HCFA) and the Federal Trade Commission (FTC) have asked FDA to assess the validity, accuracy, and effectiveness of "in vitro" cytotoxic testing as a diagnostic tool. FDA is concerned that businesses may begin distributing kits for cytotoxic testing for which efficacy has not been established.

In a letter dated September 28, 1984, the Joint Council of Allergy and Immunology stated the Council's continued concern regarding the marketing of the cytotoxic test for the diagnosis of allergic diseases and formally requested an updated summary of the agency position on cytotoxic testing.

The cytotoxic test as addressed in this guide refers to any "in vitro" test procedure for the diagnosis of allergy or intolerence to food and ingested substances employing procedures similar to those initially reported by Black in 1956 (1/) and further described by Bryan and Bryan. (2/ - 4/)

The procedure is represented as capable of identifying the presence of specific food allergy or food intolerence based on changes in the appearance, size, shape or integrity of leukocytes that are exposed to extracted food antigens or other materials derived from specific foods. The test has been identified by a variety of names, including the leukocytotoxicity test, the leukocytic food allergy test, the cytotoxic leukocyte test, or, in advertisements in the lay press simply as the CYTOTOXIC test. Over the past several years, a number of experts and scientific groups have reviewed the cytotoxic test literature and have concluded that the test is unproven. This literature has now also been reviewed by FDA staff and they have reached the same conclusion (see bibliography).

FDA's review of agency records shows that there is no FDA-regulated product on the market that has been demonstrated to be effective in cytotoxic testing nor has any manufacturer submitted evidence to support the marketing of any new product for the cytotoxic test.

FDA has determined that the cytotoxic test remains, in 1985, as an unproven diagnostic procedure unsupported by the scientific literature or well-controlled studies and clinical trials. While there are several reports of uncontrolled studies in the literature which advocate the use of the cytotoxic test, the consensus of scientific opinion is that the cytotoxic test is unreliable as a diagnostic tool and is not generally recognized by qualified experts as effective.

POLICY:

It is the agency position that cytotoxic test kits are devices as that term is defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act. Cytotoxic test kits promoted or offered for the diagnosis of allergic diseases would be adulterated and misbranded unless approval has been granted by FDA. The sections of the Act that would be violated are: (1) section 501(f)(1)(B), in that an application under section 515 has not been approved and the device is not exempt from premarket approval under the Investigational Device Exemption (IDE) provisions of section 520(g); (2) section 502(a), in that the labeling is false and misleading; (3) section 502(f)(1), in that the device fails to bear adequate directions for lay use of the product and is not exempt under 21 CFR 801.109 (Rx legend); and (4) section 502(o) in that the firm has not registered under section 510, has failed to file a list as required by section 510(j), and was not the subject of a notice or other information as required under section 510(k).

The agency will consider appropriate regulatory action to enforce the statute, should violative test kits be discovered.

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