Nomenclature for Monoclonal Blood Grouping Reagents (9/28/92)

Date: 9/28/92

From: Director, Center for Biologics Evaluation and Research

Subject: Nomenclature for Monoclonal Blood Grouping Reagents

To: U.S. Licensed Manufacturers of Blood Grouping Reagents

During the November 1990 workshop, "Reagents for the 1990's", questions arose regarding the appropriate nomenclature for the Monoclonal Blood Grouping Reagent that replaces group O sera (anti-A,B) and reacts with both the A antigen and its subgroups as well as the B antigen and its subgroups. This product is currently called "Anti-A and B" in the United States when the source material is monoclonal antibody or a blend of monoclonal antibodies; some countries have called it "Anti-A/B" or "Anti-A+B". The corresponding polyclonal products have always been labeled "Anti-A,B" in the United States.

Consistent with the comments presented at the workshop, the Center for Biologics Evaluation and Research (CBER) recommends the following nomenclature changes to afford consistency, facilitate labeling, and eliminate consumer confusion.

Blood Grouping Reagent which reacts with both the A antigen and its subgroups as well as the B antigen and its subgroups, regardless of its source, should be called "Anti-A,B." Reactivity with a majority of group A(x) cells is required and must be documented. Claims of reactivity with any other subgroups must be documented as well.

The labeling must indicate if the source material is a single monoclonal antibody or a blend of two or more such antibodies. However, indication that the product consists of a blend of two or more monoclonal antibodies need not appear in the proper name of the product, provided an accurate description is included in the "Reagents" section of the package insert.

The term "Anti-A and B" can be phased out by manufacturers as they exhaust their labeling supplies, since the package insert will continue to permit consumers to determine the specific reactivity of each product. As a result, the availability of products with both kinds of labeling for a short period of time will not cause confusion.

Manufacturers of product for further manufacturing use may request approval for the use of other nomenclature, provided appropriate rationale and data in support of the request are supplied.

Requests to change the labeling of "Anti-A and B" to "Anti-A,B" or for the use of other nomenclature should be submitted as part of the Transmittal of Labels and Circulars, FORM FDA 2567 for review and approval by CBER. All changes should be highlighted in each labeling submission to expedite review and approval.

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