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because of interest in dietary supplements and drug substances arising from rDNA technology. At this time, USAN does not consider names for many complex drug substances but rather focuses only on fully characterized specific moieties and combinations thereof.

II. Conjugated Estrogens

Conjugated estrogens is a partially characterized complex drug substance of animal origin that has been marketed under the brand name of Premarin in the United States since 1942. A need for names for conjugated estrogens mixtures arises because of interest from other sponsors in developing conjugated estrogen mixtures that may or may not be pharmaceutically equivalent to Premarin.

III. Factors

The following factors were considered in naming conjugated estrogen mixtures: 1) source (natural or synthetic); 2) extent and type of conjugation (sulfate or glucuronide conjugates); 3) presence of non-estrogenic moieties; 4) consistency; 5) brevity; 6) clarity; and 7) prior naming conventions for other complex drug substances. All factors were considered in light of the understanding that the primary audience for a non-proprietary name is the practitioner and patient. Recognizing that different natural source and synthetic mixtures of conjugated estrogens might be approved as new drugs, the proposed nomenclature is intended to be flexible.

IV. Recommendations

The source of the product, natural or synthetic, to signal that the substance is well-characterized, should be a modifier for "conjugated estrogens." The name will be further defined with an letter for each subsequent different mixture, depending on sequence of approval. The type of conjugation should not be distinguished because the amount of non-sulfated conjugates present is very small, as well as for the reason of brevity. Because synthetic CE mixtures may be a subset of natural conjugated estrogens with respect to components and composition, it is appropriate for them to be called conjugated estrogens as well.

According to the general approach, the name for currently available conjugated estrogens would be Natural Conjugated Estrogens A. Other pharmaceutically inequivalent natural source conjugated estrogens, approved as pioneer drugs, would be named Natural Conjugated Estrogens B. The proposed name for the Duramed nine component synthetic conjugated estrogens drug substance would be Synthetic Conjugated Estrogens A. Should a ten component mixture of synthetic conjugated estrogens be approved, the recommended name would be Synthetic Conjugated Estrogens B.