exposure to this color additive. Therefore, the agency proposes to amend § 74.706 to require that the labeling of butter, cheese, and ice cream that contain FD&C Yellow No. 6 include a declaration of the presence of this color additive in the list of ingredients.

To minimize the economic impact of imposing this requirement, the agency is proposing that any final rule that may issue based upon this proposal become effective 2 years after its publication in the **Federal Register**. However, the agency solicits comments on whether a different effective date is appropriate.

B. Drugs

The use of color additives in drugs for human use is an old, accepted practice in the pharmaceutical industry. The use of color additives in drugs serves a necessary public health function because it permits drugs of identical size and shape to be distinguished. The distinguishing characteristic provided by the use of color additives is an important quality control tool in dispensing drugs to prevent mixups among otherwise similarly appearing products. The ability to distinguish among products is also important to persons taking more than one drug, especially to the patient who may think in terms of taking a drug of a particular color rather than by name of the drug. Color additives in drugs also assist in the identification of a drug in cases of accidental overdose.

Because yellow is a primary color, yellow color additives are widely used in coloring drug products. A substantial number of drug products would have to be reformulated if FD&C Yellow No. 6 were prohibited in drugs for human use. If prohibition of FD&C Yellow No. 6 from use in drugs were found to be necessary to protect the public health, the considerable time and effort necessary to reformulate drugs and the loss of product identification would be unimportant. However, on the basis of the available information concerning the nature and extent of possible intolerance to FD&C Yellow No. 6, the agency tentatively concludes that prohibiting all drug uses of FD&C Yellow No. 6 is not necessary, and that requiring labeling similar to that for foods will ensure the protection of patients who may be intolerant of FD&C Yellow No. 6.

Therefore, the agency is proposing to require label declaration of FD&C Yellow No. 6 when the color additive is present in prescription and over-the-counter (OTC) drug products administered orally, nasally, rectally, or vaginally. Other modes of exposure are not expected to trigger an allergic response. As discussed in section III.A. of this document, authority for this action is provided by section 721(b)(3) of the act, which states that the regulations for the listing of a color additive shall prescribe the conditions, including directions or other labeling or packaging requirements, under which the color additive may be safely used.

In the **Federal Register** of November 19, 1986 (51 FR 41765) and June 8, 1987 (52 FR 21505), FDA established §§ 74.1706(c)(2) and 201.20(c) (21 CFR 74.1706(c)(2) and 201.20(c)). These regulations provided requirements for the label declaration of FD&C Yellow No. 6 in certain drug products. As discussed in Section I of this document, in the **Federal Register** of December 6, 1988 (53 FR 49138), the agency issued a final rule that suspended §§ 74.706(d)(2), 74.1706(c)(2), and 201.20(c) pending further agency action. The agency is now proposing to adopt these regulations.

Under the proposed §§ 74.1706(c)(2) and 201.20(c), prescription and over-the-counter (OTC) drug products administered orally, nasally, rectally, or vaginally will be required to declare the presence of FD&C Yellow No. 6 by listing the color additive using the name FD&C Yellow No. 6. Topical or other externally applied drug products are not subject to these proposed regulations. If these proposed regulations are adopted, holders of approved applications for drug products containing FD&C Yellow No. 6 will be required to describe a labeling change to comply with the rule in accordance with § 314.70(d)(2) (21 CFR 314.70(d)(2)).

The agency is proposing that any final rule that may issue based upon this proposal become effective 2 years after its publication in the **Federal Register**, the same effective date proposed previously for labels of butter, cheese, and ice cream containing FD&C Yellow No. 6. Any drug product that is initially introduced or initially delivered for introduction into interstate commerce after the effective date would be misbranded under section 502 of the act (21 U.S.C. 352) if not in compliance with this proposed rule. However, the agency solicits comments on whether a different effective date is appropriate.

IV. Conforming Amendments

In the **Federal Register** of January 6, 1993 (58 FR 2891), the agency amended the cheese standards in part 133 (21 CFR part 133) to bring them into conformity with the requirements of the 1990 amendments. For the declaration of color additives, the amended cheese standards refer to the applicable sections of 21 CFR parts 101 and 130. However, in that document, the agency overlooked a provision in the standard of identity for cold-pack and club cheese (§ 133.123) that ''Artificial coloring need not be declared.'' The agency notes that this provision is redundant because § 101.22(k)(3) provides that artificial coloring added to butter, cheese, or ice cream need not be declared unless such declaration is required by a regulation in 21 CFR part 73 or 74. Furthermore, this provision may create confusion, because, under § 74.705(d)(2), FD&C Yellow No. 5 is required to be declared in the ingredient list on the labels of butter, cheese, and ice cream when the color additive is used in these products, and now the agency is proposing the same requirement for FD&C Yellow No. 6. Therefore, the agency is proposing to amend the standard of identity for cold-pack and club cheese in § 133.123 by removing paragraph (f)(1), that provides that artificial color need not be declared. With the removal of this provision, all of the cheese standards will be subject to the labeling provisions of § 130.3(e) and thus, the requirements of § 101.22 (c) and (k). Moreover, the agency notes that § 133.123(f)(2) unnecessarily repeats part of the first sentence of § 133.123(f). Therefore, to make this cheese standard consistent with the other cheese standards in part 133 and to eliminate this redundancy, the agency is also proposing to remove § 133.123(f)(2).

Also, the agency is proposing to revise the current labeling requirement for FD&C Yellow No. 5, which requires that foods that contain FD&C Yellow No. 5, including butter, cheese, and ice cream, declare the color additive as ''FD&C Yellow No. 5'' (21 CFR 74.705(d)(2)). The agency's new labeling requirements in § 101.22(k)(1) allow for the use of abbreviated names of certified color additives on food labels. For example, FD&C Yellow No. 5 may be declared either by its full name as ''FD&C Yellow No. 5'' or by an appropriate abbreviation, such as ''Yellow 5.'' Therefore, to prevent any confusion over label declaration of FD&C Yellow No. 5, the agency is proposing to revise § 74.705(d)(2) to state that the labels of butter, cheese, and ice cream that contain FD&C Yellow No. 5 shall declare the color additive in accordance with § 101.22(k)(1). The agency is also proposing to remove the statement ''Foods for human use'' in the current § 74.705(d)(2), because the 1990 amendments made it mandatory to declare the certified color additives on labels of foods for human use, other than butter, cheese, and ice cream, and