

WORLD TRADE ORGANIZATION

RESTRICTED

G/SPS/N/USA/24

18 March 1996

(96-0955)

Committee on Sanitary and Phytosanitary Measures

NOTIFICATION

1.	Member to Agreement notifying: <u>UNITED STATES</u> If applicable, name of local government involved:
2.	Agency responsible: Food and Drug Administration (24)
3.	Products covered (tariff item number(s) as specified in national schedules deposited with the WTO. ICS numbers may be provided in addition, where applicable): Colour additives
4.	Title and number of pages of the notified document: Permanent Listing of Colour Additive Lakes (46 pages)
5.	Description of content: The Food and Drug Administration is proposing to list certain colour additive lakes permanently as suitable and safe for use in food (notified under the SPS Agreement), drugs, and cosmetics (notified under the TBT Agreement). The Agency is proposing to permit the use of more than one straight colour in the preparation of a lake, to modify the nomenclature for lakes, and simplify the batch certification procedure for lakes. As part of these actions, the Agency is proposing to amend its regulations to require the preparation of lakes from certified batches of straight colour; to provide simplified nomenclature for declaring colour additives, including lakes, on cosmetic products; to require declaration of FD&C Yellow No. 5 and FD&C Yellow No.6 on all foods and some drug products containing lakes of these straight colours; and to terminate the listing of certain straight colours as components of lakes for drugs and cosmetic use and the listing of calcium salts as components of lakes for food use.
6.	Objective and rationale: This proposed rule is intended to complete the Agency's disposition of the provisions list of colour additives that was established under the transitional provisions of the colour additive amendment of 1960 and to establish regulations prescribing conditions under which lakes may be prepared, labelled, and safely used in food, drugs and cosmetics.

7.	An international standard, guideline or recommendation does not exist [X]. If an international standard, guideline or recommendation exists, whenever possible, identify deviations:
8.	Relevant documents: 61 FR 8372, 4 March 1996; 21 CFR Parts 70, 73, 74, 80, 81, 82, 101, 178, 201 and 701. This proposal was also notified under the Agreement on Technical Barriers to Trade (TBT).
9.	Proposed date of adoption and entry into force: The effective date will be given upon publication of the final rule in the Federal Register.
10.	Final date for comments: Written comments by 3 June 1996, except that comments regarding information collection should be submitted not later than 3 May 1996.
11.	Texts available from: National enquiry point [] or address and telefax number of other body: United States SPS Enquiry Point USDA/FAS/OPSTS Attn: Carolyn F. Wilson Room 5545 South Agriculture Building 14th and Independence Washington, D.C. 20250 Phone: (202) 720-2239 Fax: (202) 690-0677