manufacturers of this proposed regulation is expected to be negligible. Manufacturers could, of course, revise their labeling before the effective date of the regulation, and the agency encourages them to do so.

b. *Costs to the drug industry.* There are 815 currently marketed prescription and OTC drug products that are administered to mucous membranes (through oral, nasal, rectal or vaginal routes) and that contain FD&C Yellow No. 6. The cost of printing a drug label is estimated to be $258 per label. Therefore, the printing cost associated with this proposed regulation is estimated to be $210,270. FDA assumes that almost all existing label stocks for drug products will be depleted by the proposed effective date. Therefore, this proposed regulation will result in little or no inventory disposal costs. Administrative costs are estimated to be approximately $850 per firm. FDA estimates that approximately 113 firms will be affected by this regulation. Therefore, the administrative costs are estimated to be $96,050. The total one-time cost to the drug industry of declaring FD&C Yellow No. 6 on the label is $306,320.

2. Benefits

The benefit of requiring the labeling of FD&C Yellow No. 6 on butter, cheese, ice cream, and drug products administered to mucous membranes is ultimately the reduction of allergic-type reactions. FDA does not have information to quantify the benefits of this proposed regulation.

C. Summary

FDA has determined that this proposed rule is not a significant rule as defined by Executive Order 12866. The requirement to include FD&C Yellow No. 6 on the labels of butter, cheese, ice cream, and drug products administered to mucous membranes would result in a one-time cost of about $306,000.

IX. Comments

Interested persons may, on or before October 4, 1995, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects

21 CFR Part 74

Color additives, Cosmetics, Drugs.

21 CFR Part 133

Cheese, Food grades and standards, Food labeling.

21 CFR Part 201

Drugs, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that the suspension of the effective date of 21 CFR 201.20(c) at 53 FR 49138, December 6, 1988, be removed and 21 CFR parts 74 and 133 be amended as follows:

PART 74—LISTING OF COLOR ADDITIVES SUBJECT TO CERTIFICATION

1. The authority citation for 21 CFR part 74 continues to read as follows:

Authority: Secs. 201, 401, 402, 403, 409, 501, 502, 505, 601, 602, 701, 721 of the Federal, Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e).

2. Section 74.705 is amended by revising paragraph (d)(2) to read as follows:

§ 74.705 FD&C Yellow No. 5.

* * * * *

(d) * * *

(2) Butter, cheese, and ice cream that contain FD&C Yellow No. 5 shall be labeled in accordance with § 101.22(k)(1) of this chapter.

* * * * *

3. Section 74.706 is amended by adding paragraph (d)(2) to read as follows:

§ 74.706 FD&C Yellow No. 6.

* * * * *

(d) * * *

(2) Butter, cheese, and ice cream that contain FD&C Yellow No. 6 shall be labeled in accordance with § 101.22(k)(1) of this chapter.

* * * * *

4. Section 74.1706 is amended by adding paragraph (c)(2) to read as follows:

§ 74.1706 FD&C Yellow No. 6.

* * * * *

(c) * * *

(2) The label of over-the-counter (OTC) and prescription drug products intended for human use and administered orally, nasally, rectally, or vaginally containing FD&C Yellow No. 6 shall specifically declare the presence of FD&C Yellow No. 6 by listing the color additive using the name FD&C Yellow No. 6. The labels of certain drug products subject to this labeling requirement that are also cosmetics, such as antibacterial mouthwashes and fluoride toothpastes, need not comply with this requirement provided they comply with the requirements of § 701.3 of this chapter.

* * * * *

PART 133—CHEESES AND RELATED CHEESE PRODUCTS

5. The authority citation for 21 CFR part 133 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 701, 721 of the Federal, Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 371, 379e).

§ 133.123 [Amended]

6. Section 133.123 *Cold-pack and club cheese* is amended by removing paragraphs (f)(1) and (f)(2).

Dated: July 6, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–17831 Filed 7–20–95; 8:45 am]

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21 CFR Part 101

[Docket No. 93P–0448]

Food Labeling; Serving Sizes; Reference Amount for ''Salt, Salt Substitutes, Seasoning Salts (e.g., Garlic Salt)''

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the nutrition labeling regulations to change the reference amount customarily consumed per eating occasion for the food category ''salt, salt substitutes, seasoning salts (e.g., garlic salt)'' from a weight-based reference amount of 1 gram (g) to a volume-based reference amount of 1/4 teaspoon (tsp). This action is necessary to provide consistency with the agency's criteria for determining volumetric versus weight-based reference amounts for all product categories.

DATES: Written comments by October 4, 1995.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Ellen M. Anderson, Center for Food