DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

Food and Drug Administration
College Park, MD 20740

JUL 3 2003

4366 '03 JUL 11 P2:12

Bruce Silverglade
Director of Legal Affairs
Center for Science in the Public Interest
Suite 300
1875 Connecticut Avenue, N.W.
Washington, D.C. 20009-5728

Dear Mr. Silverglade:

Thank you for your May 13, 2003, letter expressing concern with the labeling of Smucker's "Simply 100% Fruit" spreadable fruit products. You requested that the Food and Drug Administration (FDA) (1) expand its requirements for percentage ingredient labeling; (2) align its policies with international norms and support the development of an expanded percentage ingredient labeling standard by the Codex Alimentarius Commission; and (3) use FDA's current legal authority to stop misleading labeling and require the percentages of important ingredients to be disclosed.

As you know, FDA is still considering the petition received in 1997 (Docket No. 97P-0130) regarding percentage ingredient labeling. We have forwarded your letter and attachments to Docket No. 97P-0130 to be included as part of the official record.

Thank you for the continued efforts of the Center for Science in the Public Interest in gathering and evaluating the labels for the many products that you have submitted over the years. We appreciate your referral to the Center for Food Safety and Applied Nutrition (CFSAN) of product labels that you feel are in significant violation of the Federal Food, Drug, and Cosmetic Act (the act). Such information can be helpful in our enforcement of the act and useful in conducting an appropriate follow-up. We will evaluate the information you provided in light of our program and enforcement priorities.

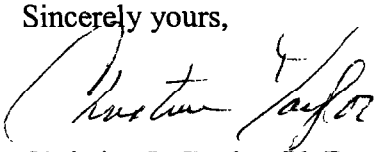
The primary priorities for CFSAN at this time are heavily focused on food security, bioterriorism and the steps needed to implement the Commissioner's Consumer Health Information for Better Nutrition Initiative. We are committed to improving opportunities for

97P-0130

ANS1

consumers to get scientifically accurate information about the health benefits of the foods they consume and to enhancing our enforcement efforts against dietary supplement marketers who make false or misleading claims for their products.

Sincerely yours,



Christine L. Taylor, Ph.D.
Director
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copy to:
Irene Ringel Heller
Senior Staff Attorney
Center for Science in the Public Interest

Joleen Okun
Research Associate
Center for Science in the Public Interest

CSPI CENTER FOR SCIENCE IN THE PUBLIC INTEREST
Publisher of *Nutrition Action Healthletter*

May 13, 2003

Joe Levitt, Director
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

Re: Request for Regulatory Action to Prohibit Misleading Labeling Claims by The J.M Smucker Company; *See,* Petition for Proposed Rulemaking and Regulatory Action to Prohibit Misleading Food Labeling (Docket No. 95P-0256) and Petition to Require Percentage Ingredient Labeling (Docket No. 97P-0130).

Dear Mr. Levitt:

Requested Action

The Center for Science in the Public Interest (CSPI) requests that the Food and Drug Administration (FDA) take regulatory action to protect consumers from misleading ingredient claims by The J.M. Smucker Company (hereinafter "Smucker's") and to ensure that consumers are provided with complete, easy-to-read information about the ingredient content of Smucker's products.

1. The FDA Should Prohibit Misleading Ingredient Claims by Smucker's.

CSPI requests that the FDA prohibit deceptive labeling claims that misrepresent the amount of fruit in Smucker's "Simply 100% Fruit" spreadable fruit products (Att. 1). Smucker's "Simply 100% Fruit Strawberry" simply is not made only from strawberries. The product actually consists of only 30% strawberries. Similarly, Smucker's "Simply 100% Fruit Blueberry" actually consists of only 43% blueberries. Both products contain more fruit syrup than fruit (69% for the strawberries and 56% for the blueberries). Moreover, the syrups are actually made from apple and pineapple juice[1] rather than the fruit named on the front label (principal display panel).

We obtained the percentages of actual fruit content from the labels of Smucker's products sold in Thailand (Att. 2). Thailand is one of at least 18 countries around the world that require the percentages of major ingredients to be listed on the label. Company representatives confirmed to CSPI that the firm's products sold overseas are made in the U.S. and are the same as

[1] Telephone conversation between Al Yeagley, Director of Corporate Quality Assurance, J.M. Smucker Company, and Bruce Silverglade, Director of Legal Affairs, CSPI, May 6, 2003.

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Michael F. Jacobson, P
Executive D

those sold here.[2]

Under U.S. law, fruit preserves and jams must contain at least 47% actual fruit,[3] but there is no minimum for spreadable fruits because they are not subject to a standard of identity. Despite the name "Simply 100% Fruit," there is significantly less fruit in that product than in the company's preserves: 30% fruit in the strawberry spread and 43% in the blueberry variety.[4]

Despite its higher percentage of fruit content, the traditional preserves cost less per ounce than the company's deceptively labeled "Simply 100% Fruit." We understand that preserves made with ordinary sugar may cost less to produce than spreadable fruits made with fruit syrup. However, many consumers who are trying to increase their consumption of fruit, as recommended by health authorities,[5] are likely to believe that they can help achieve that goal by paying more for a premium product labeled "100% Fruit." Ironically, such consumers would actually be getting significantly less nutritious fruit than if they purchased a less expensive product labeled "preserves."[6]

CSPI brought similar problems to the attention of the FDA in a petition submitted to the

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[2] Telephone call between Bruce Silverglade and Al Yeagley, May 6, 2003; Telephone call between Joleen Okun, research associate, CSPI, and Smucker's consumer relations department, April 2, 2003, Reference #6108350A. In an April 8, 2003 telephone conversation, CSPI asked how much real fruit is actually contained in the company's "Simply 100% Fruit" products. Company representatives declined to answer, arguing that the information was "proprietary" even though such information is routinely disclosed on the ingredient labels of Smucker's products sold overseas.

[3] 21 C.F.R § 150.160 (d)(1).

[4] In a telephone call by CSPI to Smucker's Consumer Relations Department, a company representative claimed that "spreadable fruits" must contain less fruit than preserves in order to be "spreadable." However, competitors of Smucker's, such as Polaner, sell spreadable fruit products that contain more than the amount of fruit required in preserves; telephone call between Joleen Okun, CSPI, and Smucker's consumer relations department, April 10, 2003. At least one competitor – B & G – sells a product called Polaner's "Spreadable Apricots" that claims to contain "More Fruit Than Standard Preserves" (in this case more than 47% minimum that is required by law, *see* 21 CFR Part 150.160(d)(1)).

[5] See, Dietary Guidelines for Americans, U.S. Department of Health and Human Services and the U.S. Department of Agriculture, 2000; World Health Organization (WHO), Report on Diet, Nutrition, and the Prevention of Chronic Diseases, 2003. The WHO report identified 14 classes of foods with protective effects against chronic diseases -- fruit led the list.

[6] If Smucker's challenges this fact, or argues that the First Amendment protects the right of the company to make such claims under the commercial free speech doctrine, then the FDA should demand that the company sponsor an FDA-run consumer research study to evaluate consumer understanding of the "100% Fruit" claim.

agency on August 2, 1995 (Docket No. 95P-0256).[7] CSPI argued at that time that a J.M. Smucker Company product called "Simply Fruit - Strawberry" was misleadingly labeled because the product contained more clarified white grape juice concentrate than strawberries. While the product's ingredient list has changed, it still contains more fruit syrup made from apple and pineapple juice than strawberries. Furthermore, it is now called "100% Simply Fruit - Strawberry."

2. The FDA Should Expand Requirements for Percentage Ingredient Labeling.

Misleading claims ideally should be banned completely. However, because the FDA has failed to do that, one way to mitigate the deceptive impact of such claims is to require companies to disclose the percentages of key ingredients. Thus, the FDA should set forth the specific circumstances and manner in which the percentages of important ingredients must be disclosed on the label. Such disclosures should be required in the ingredient list and, in the case of highlighted ingredients, on the front of the package, regardless of whether the label discloses that an ingredient is included in the form of a whole food, juice, or flavorings. The type size and style of such disclosures should be expressly specified to ensure readability.

The FDA's general rules for common or usual names require that the percent of characterizing ingredients must be declared when:

> the proportion of such ingredient(s) or component(s) in the food has a material bearing on price or consumer acceptance or when the labeling or the appearance of the food may otherwise create an erroneous impression that such ingredient(s) or component(s) is present in an amount greater than is actually the case.[8]

The general principle encompassed in this regulation, however, has rarely been implemented by the agency and has not been embraced voluntarily by the food industry.[9]

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[7] CSPI's 1995 petition also named Polaner "All Fruit," manufactured by B & G Foods, Inc., and Sorrel Ridge "100% Fruit" manufactured by Allied Old English, Inc.

[8] 21 C.F.R. § 102.5(b).

[9] The FDA has issued four common or usual name regulations requiring that the percent of a characterizing ingredient be declared: 21 C.F.R. §§ 102.23 (peanut spreads), 102.33 (beverages that contain fruit or vegetable juice), 102.37 (mixtures of edible fat or oil and olive oil), and 102.54 (seafood cocktails). Although the agency has not implemented its general policy beyond these four foods, it stressed in 1993 that "The agency emphasizes . . . that the percentage of characterizing ingredients must be declared, as provided in § 102.5(b) . . ." 58 Fed. Reg. 2850, 2865 (Jan. 6, 1993).

3. The FDA Should Align its Policies with International Norms and Support the Development of an Expanded Percentage Ingredient Labeling Standard by the United Nations Codex Alimentarius Commission.

CSPI petitioned the FDA in 1997 to harmonize its regulations in this area with those of the European Union, which already requires percentage ingredient labeling for many major ingredients (Docket No. 97P-0130). American companies doing business in Europe comply with those regulations. Furthermore, Australia and New Zealand have finalized similar requirements for percentage ingredient labeling, and the Codex Alimentarius Commission's Committee on Food Labeling (CCFL) is reconsidering its existing international standard in this area. Thailand has maintained similar requirements for more than a decade. These facts call for a timely and proactive response by the FDA to protect American consumers by developing and enforcing policies consistent with the emerging international consensus in support of percentage ingredient labeling of important ingredients in prepackaged foods.

It is unconscionable that for years the FDA has failed to protect consumers from deceptions that have both health and economic consequences. Although we are well aware of the FDA's staffing constraints, it would be disingenuous for the FDA to attribute its lack of action to its scarcity of funds. It is noteworthy that the U.S. government delegation to the Codex Committee on Food Labeling (CCFL), which the FDA leads, has opposed expanded international standards for percentage ingredient labeling that could serve as a model for FDA action. We further note that food-industry trade associations representing multinational companies have urged the FDA not to support further work on this matter by Codex.[10] Thus, we surmise that FDA inaction in this area is not the result of limited resources, but rather the latest manifestation of the Agency's reluctance to support a measure opposed by the food industry even though the measure could improve consumer protection and further consumer health.

4. The FDA has Ample Legal Authority to Stop Misleading Labeling by Smucker's and Require Percentage Ingredient Labeling.

The FDA has the authority to take the actions requested here under sections 201(n), 403(a), 403(f), 403(i), and 701(a) of the FFDCA.[11] Section 701(a) authorizes the agency to adopt regulations for the "efficient enforcement of this Act."[12] Section 403(a) prohibits labeling that is "false or misleading in any particular."[13]

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[10] Smucker's products are distributed in 45 countries. Thus, companies like Smucker's have a great interest in the development and application of international standards developed by Codex.

[11] 21 U.S.C. §321(n), §343(a), §343(f), §343(i), and §371(a).

[12] 21 U.S.C. §371(a).

[13] 21 U.S.C. § 343(a). *See American Frozen Food Institute v. Mathews*, 413 F.Supp. 548 (D.C. Cir. 1976), *affirmed*, 555 F.2d 1059 (1977); *United States v. Vitasafe Formula*, 226

In determining whether the labeling is misleading, section 201(n) states that "representations made or suggested by statement, word, design, device, or any combination thereof" shall be taken into account, as well as the extent to which the labeling fails to reveal facts material to any such representations.[14] The percent of fruit contained (or purportedly contained) in preserves or a spread is material to the purchasing decision. Why else would Smucker's be able to command a higher price for its 100% fruit products than it can for a product that actually contains more fruit?

The FDA has relied on its misbranding and rulemaking authority to prescribe requirements for affirmative disclosures. For example, more than 50 years ago, the FDA recognized that a cookie product could only be referred to as "butter flavored," not merely "butter cookie" if shortenings other than butter were used in the product. That is because consumers likely interpreted the unqualified use of the word "butter" to mean that the only shortening ingredient in the product was butter. FDA required the cookie product to be re-labeled "Butter flavored cookies" provided the ingredient list stated the percentages of various shortenings used in the product, i.e. "6 percent butter, 94 percent other shortening."[15] More recently, the FDA required affirmative disclosures in conjunction with its nutrient claims regulations.

In addition, section 403(i) of the Act states that a food product not subject to a standard of identity will be considered misbranded unless its label includes the common or usual name of the food.[16] Without an appropriate common or usual name, a label does not adequately inform consumers of the true nature of the product.

The FDA's "common or usual name" regulations require that a food label accurately

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F.Supp. 266 (D.C.N.J. 1963), *remanded on other grounds*, 345 F.2d 846, *cert. denied*, 382 U.S. 918 (any single misleading, ambiguous or overemphasized statement or representation in labeling of a food renders it misbranded); *V.E. Irons, Inc. v. United States*, 244 F.2d 34, 42 (C.A. Mass. 1957) *cert. denied*, 354 U.S. 923 (1958) (the intent of the act is to prevent deception whether by "palpably false claims" or by "clever indirection and ambiguity in the creation of misleading impressions.")

[14] 21 U.S.C. § 321(n). The recommended "disclosure" approach for remedying many of the misleading labeling practices discussed in this document is based on this section of the FDCA, which provides that a material omission can render a label misbranded. This approach is consistent with the approach followed by the FDA in its nutrient content claim regulations, which require that certain claims be accompanied by disclosure statements in order to prevent deception. For example, a "reduced," "lower," "less," or "light" claim must be accompanied by a statement that discloses the amount of the particular nutrient in the product and in the relevant reference food. *See, e.g.*, 56 Fed. Reg. 60421, 60446 (1991); 21 C.F.R. §101.62(b)(4).

[15] Food, Drug, Cosm. Law Reports (CCH), ¶ 50,124.21 (TC-92), Feb. 21, 1940.

[16] 21 U.S.C. § 343(i).

identify or describe the basic nature of the food or its characterizing properties or ingredients.[17] FDA regulations also specify that the common or usual name of a product should include the percentage of any characterizing ingredient when this percentage has a material bearing on price, on consumer acceptance, or when the labeling creates an erroneous impression that said ingredient is present in an amount greater than is actually the case.[18] As previously mentioned, the FDA's common or usual name regulations could provide a template for action, but the agency has ignored this area.

In brief, the FDA has ample authority to take the actions requested in this petition that are necessary to protect both consumers' health and pocketbooks.

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[17] 21 C.F.R. § 102.5(a).

[18] 21 C.F.R. § 102.5(b).

Conclusion

It is essential that the FDA sides with the interests of consumers and ensures that the public's health is not undermined by label claims that imply that food products contain substantial amounts of nutritious ingredients, such as fruits, when this is not the case. The FDA should prohibit deceptive claims made by Smucker's and require that the percentages of important ingredients be disclosed.

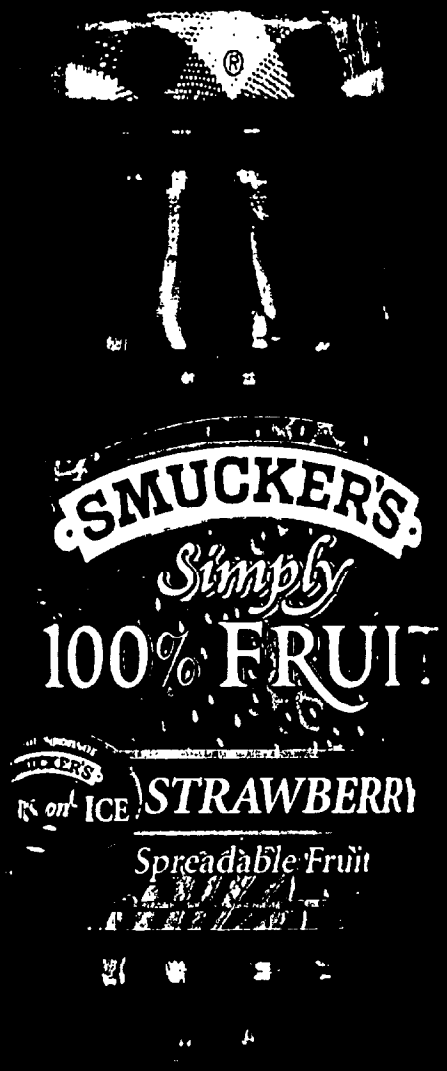
Sincerely,

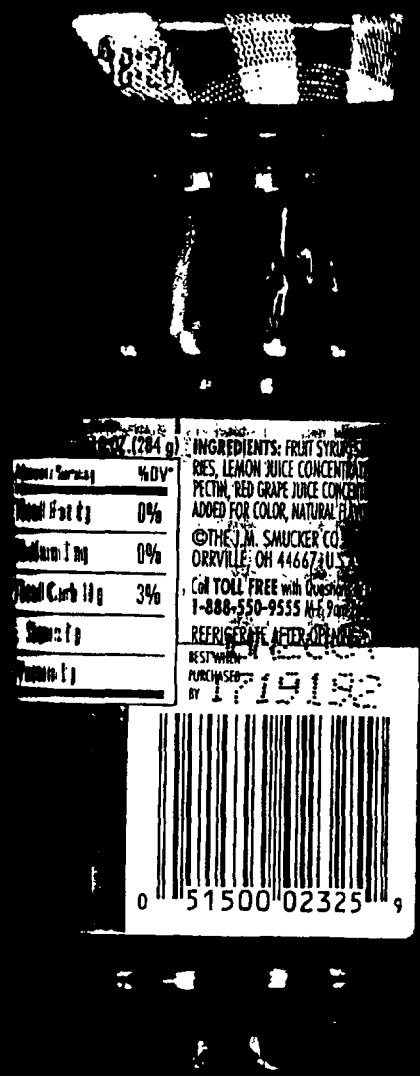
Bruce Silverglade
Director of Legal Affairs

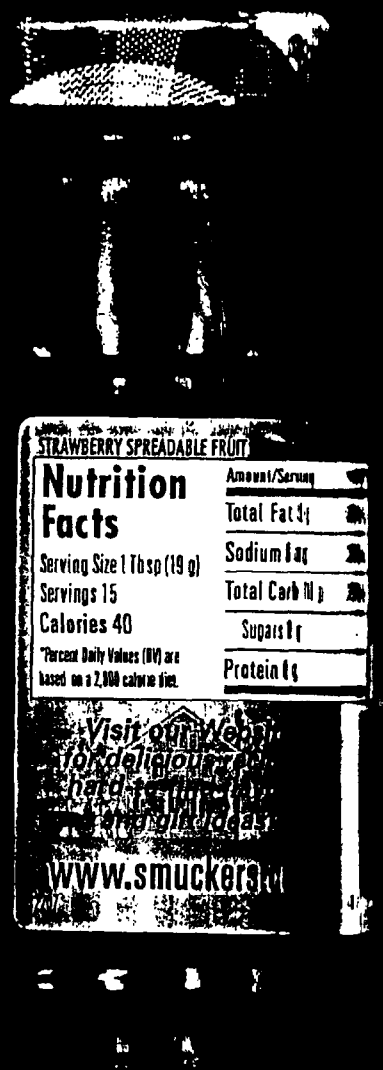
Ilene Ringel Heller
Senior Staff Attorney

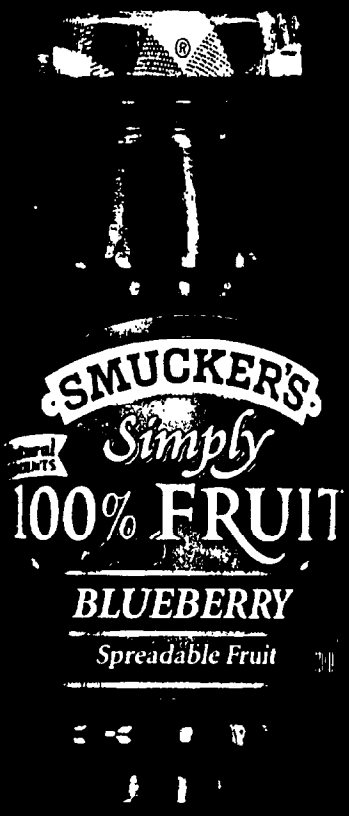
Joleen Okun
Research Associate

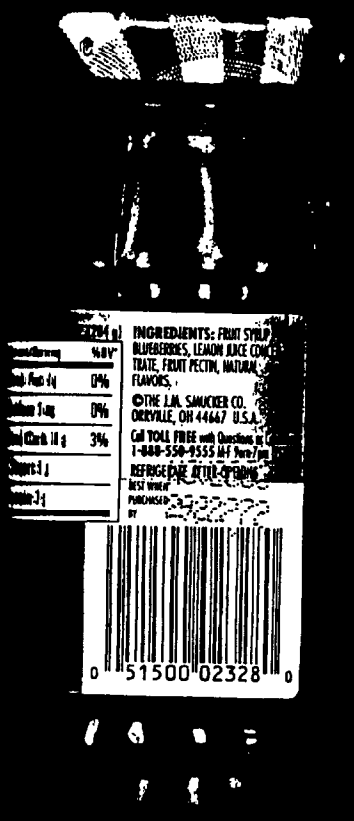
Attachment 1




%DV*
0%
0%
3%
INGREDIENTS: FRUIT SYRUP
RIES, LEMON JUICE CONCENTRATE
PECTIN, RED GRAPE JUICE CONCENTRATE
ADDED FOR COLOR, NATURAL FLAVOR
©THE J.M. SMUCKER CO.
ORRVILLE, OH 44667 U.S.A.
Call TOLL FREE with Questions
1-888-550-9555 M-F 8-5
REFRIGERATE AFTER OPENING
BEST WHEN PURCHASED BY
0 51500 02325 9


STRAWBERRY SPREADABLE FRUIT
Nutrition Facts
Serving Size 1 Tbsp (19 g)
Servings 15
Calories 40
*Percent Daily Values (DV) are based on a 2,000 calorie diet.
Amount/Serving
Total Fat 0g
Sodium 0mg
Total Carb 10g
Sugars 8g
Protein 0g
www.smucker


SMUCKER'S
Simply
100% FRUIT
BLUEBERRY
Spreadable Fruit


INGREDIENTS: FRUIT SYRUP
BLUEBERRIES, LEMON JUICE CONCENTRATE, FRUIT PECTIN, NATURAL FLAVORS.
©THE J.M. SMUCKER CO.
ORRVILLE, OH 44667 U.S.A.
Call TOLL FREE with Questions or
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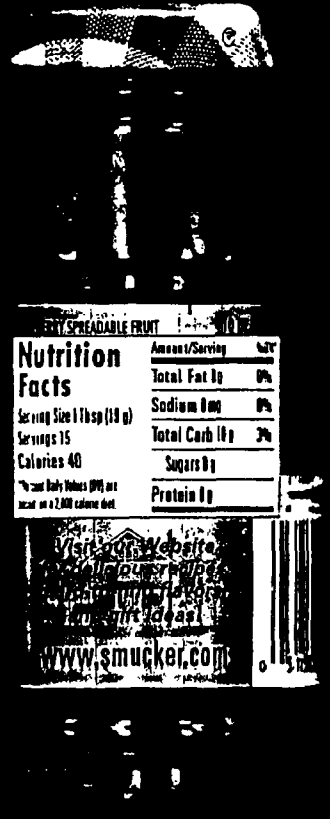
Nutrition Facts
Serving Size 1 Tbsp (18 g)
Servings 15
Calories 40
Amount/Serving
Total Fat 0g
Sodium 0mg
Total Carb 10g
Sugars 8g
Protein 0g
www.smucker.com

SMUCKER'S

STARS

Strawberry
Preserves

12 OZ (340g)

INGREDIENTS: STRAWBERRIES, HIGH FRUCTOSE CORN SYRUP, CORN SYRUP, SUGAR, FRUIT PECTIN, CITRIC ACID.

ORRVILLE, OH 44667 U.S.A.

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1-888-550-9555 M-F 9am-7pm (EST).
REFRIGERATE AFTER OPENING

BEST WHEN
USED BY

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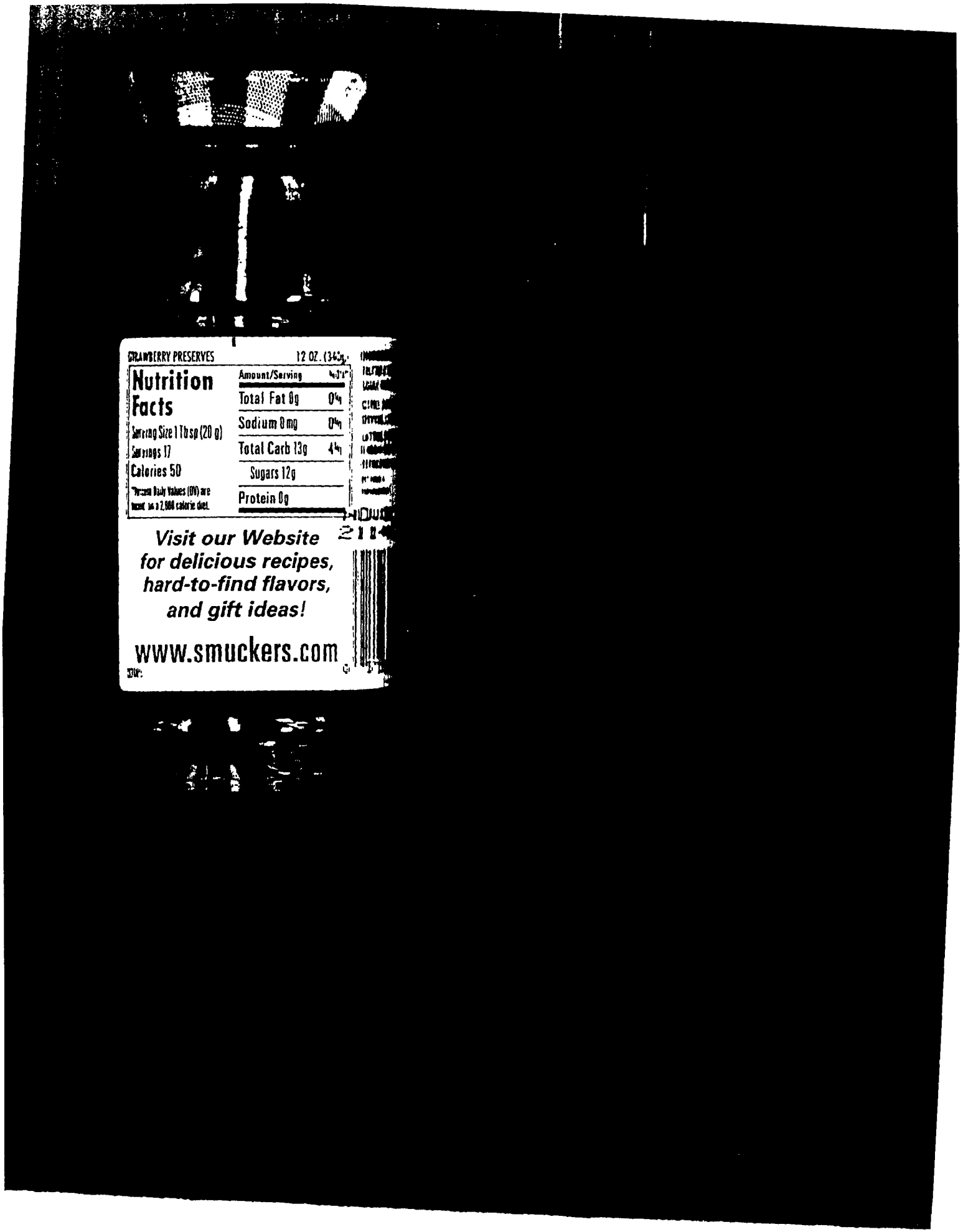
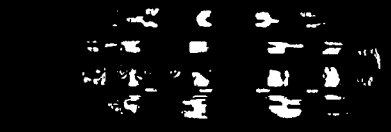
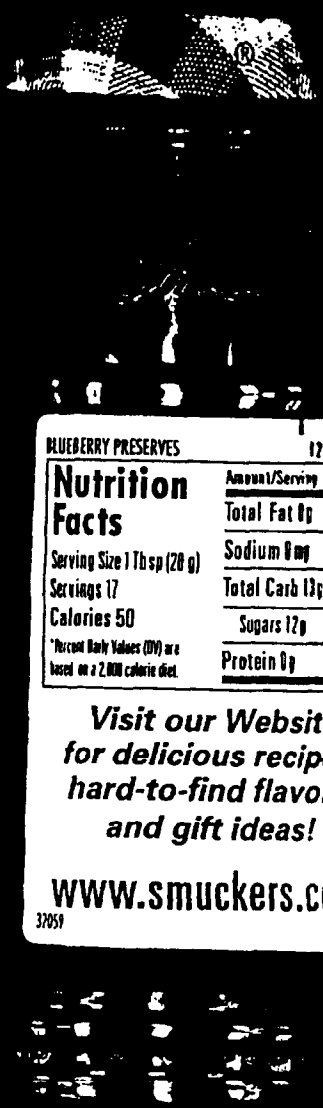

STRAWBERRY PRESERVES
12 OZ. (340g)
Nutrition Facts
Serving Size 1 Tbsp (20 g)
Servings 17
Calories 50
*Percent Daily Values (DV) are based on a 2,000 calorie diet.
Amount/Serving
Total Fat 0g
Sodium 0mg
Total Carb 13g
Sugars 12g
Protein 0g
Visit our Website for delicious recipes, hard-to-find flavors, and gift ideas!
www.smuckers.com

Blueberry
Preserves




BLUEBERRY PRESERVES
12 OZ.
Nutrition Facts
Serving Size 1 Tbsp (20 g)
Servings 17
Calories 50
*Percent Daily Values (DV) are based on a 2,000 calorie diet.
Amount/Serving
Total Fat 0g
Sodium 0mg
Total Carb 13g
Sugars 12g
Protein 0g
Visit our Website for delicious recipes, hard-to-find flavors, and gift ideas!
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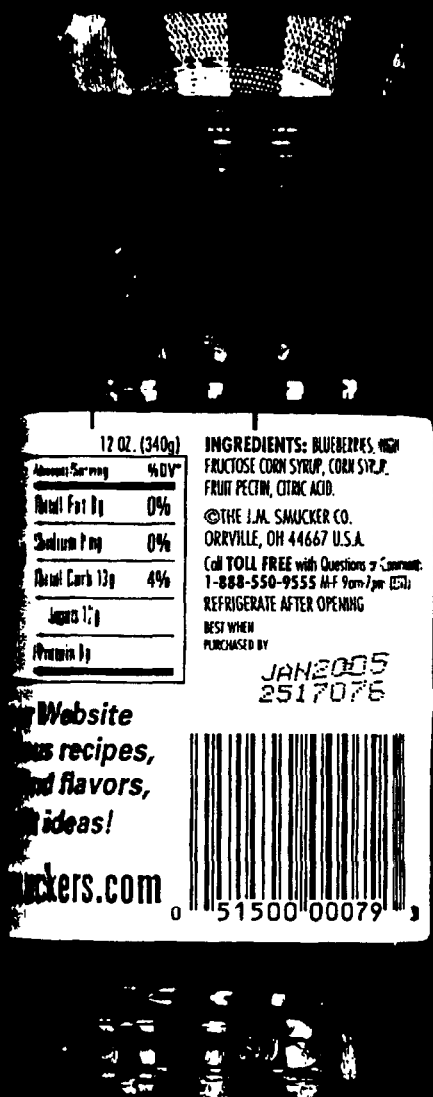
37059



12 OZ. (340g)

Amount Per Serving	%DV*
Total Fat 0g	0%
Sodium 0mg	0%
Total Carb 13g	4%
Sugars 12g	
Protein 0g	

INGREDIENTS: BLUEBERRIES, HIGH FRUCTOSE CORN SYRUP, CORN SYRUP, FRUIT PECTIN, CITRIC ACID.

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JAN2005
2517076

Website
recipes,
flavors,
ideas!

uckers.com

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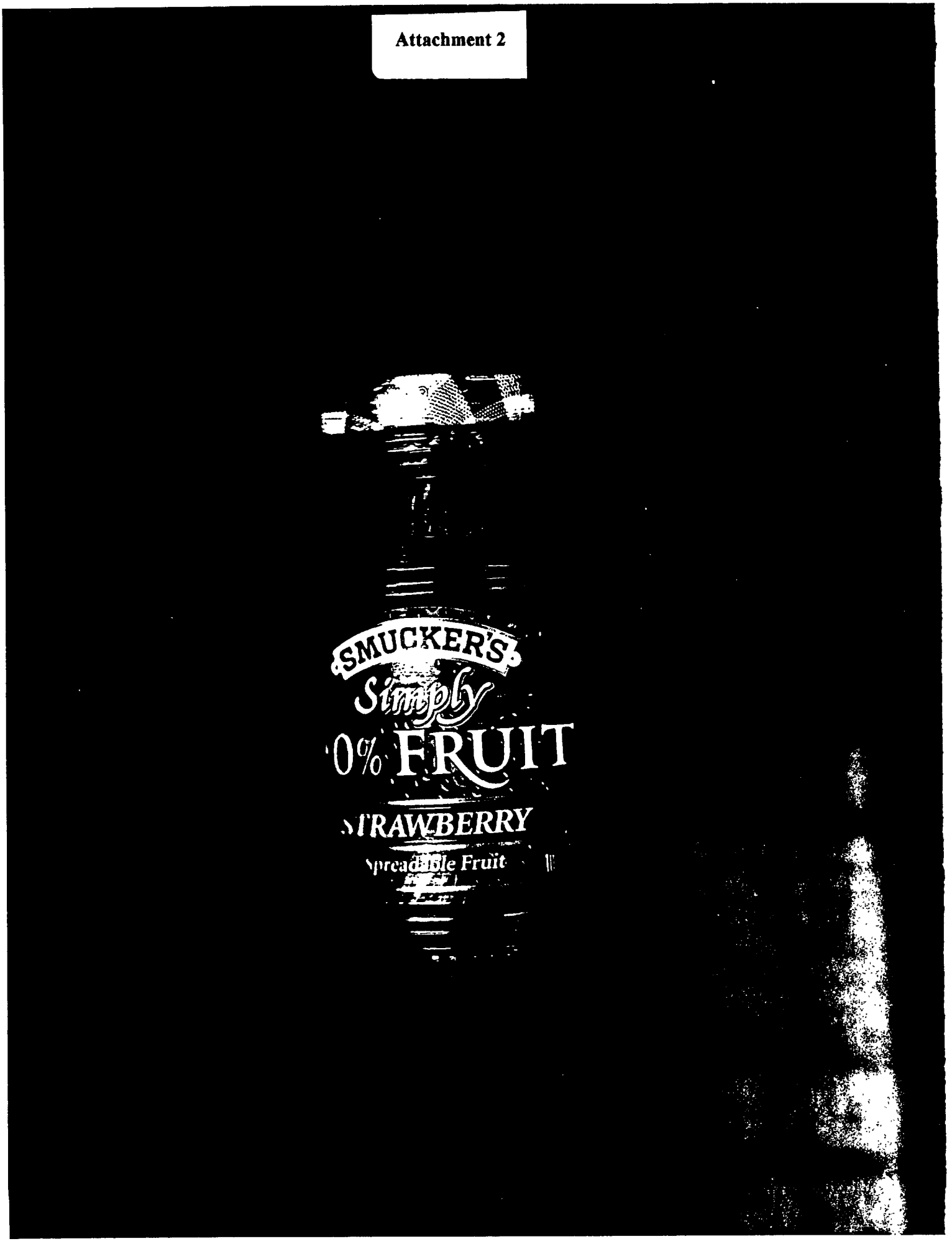
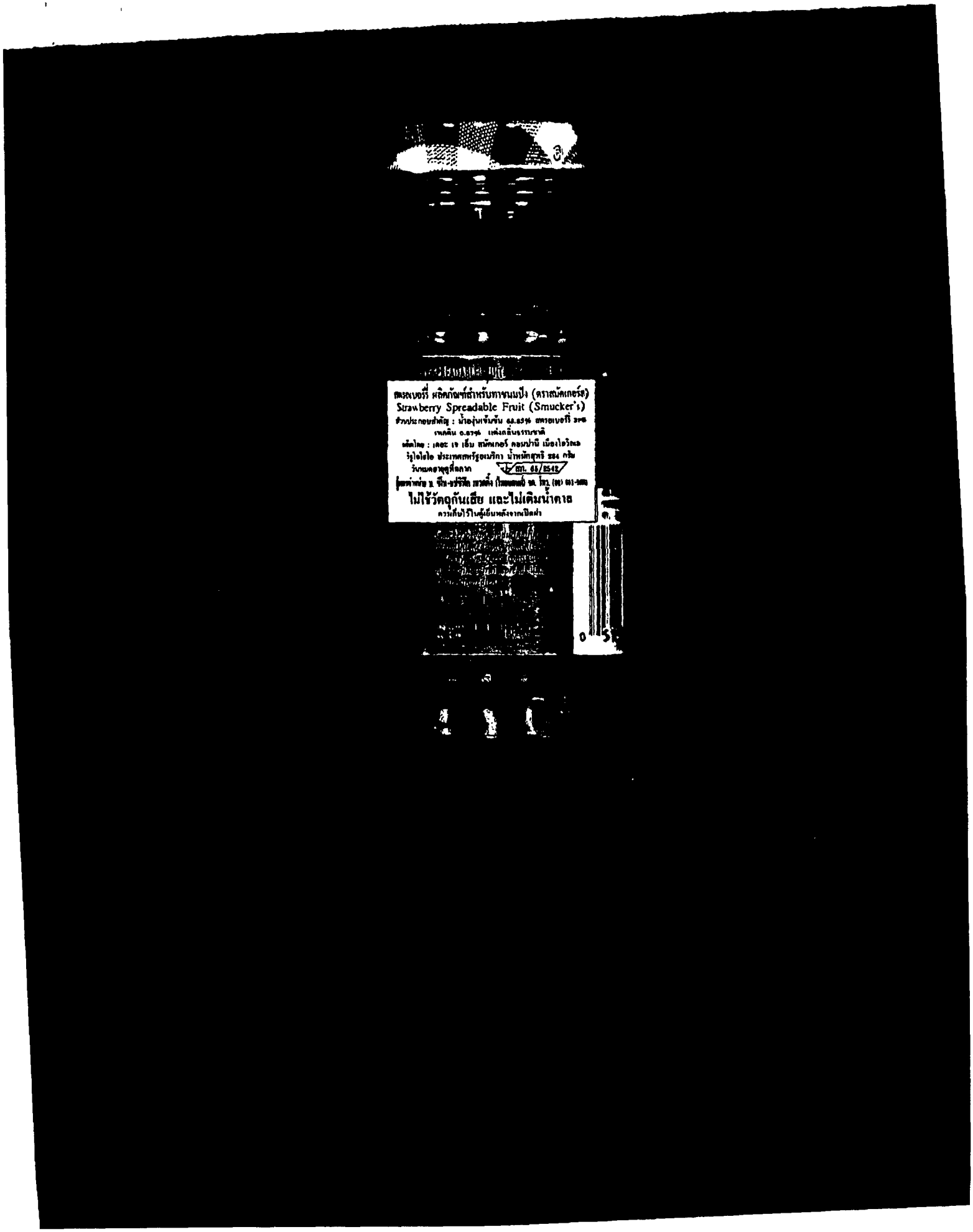
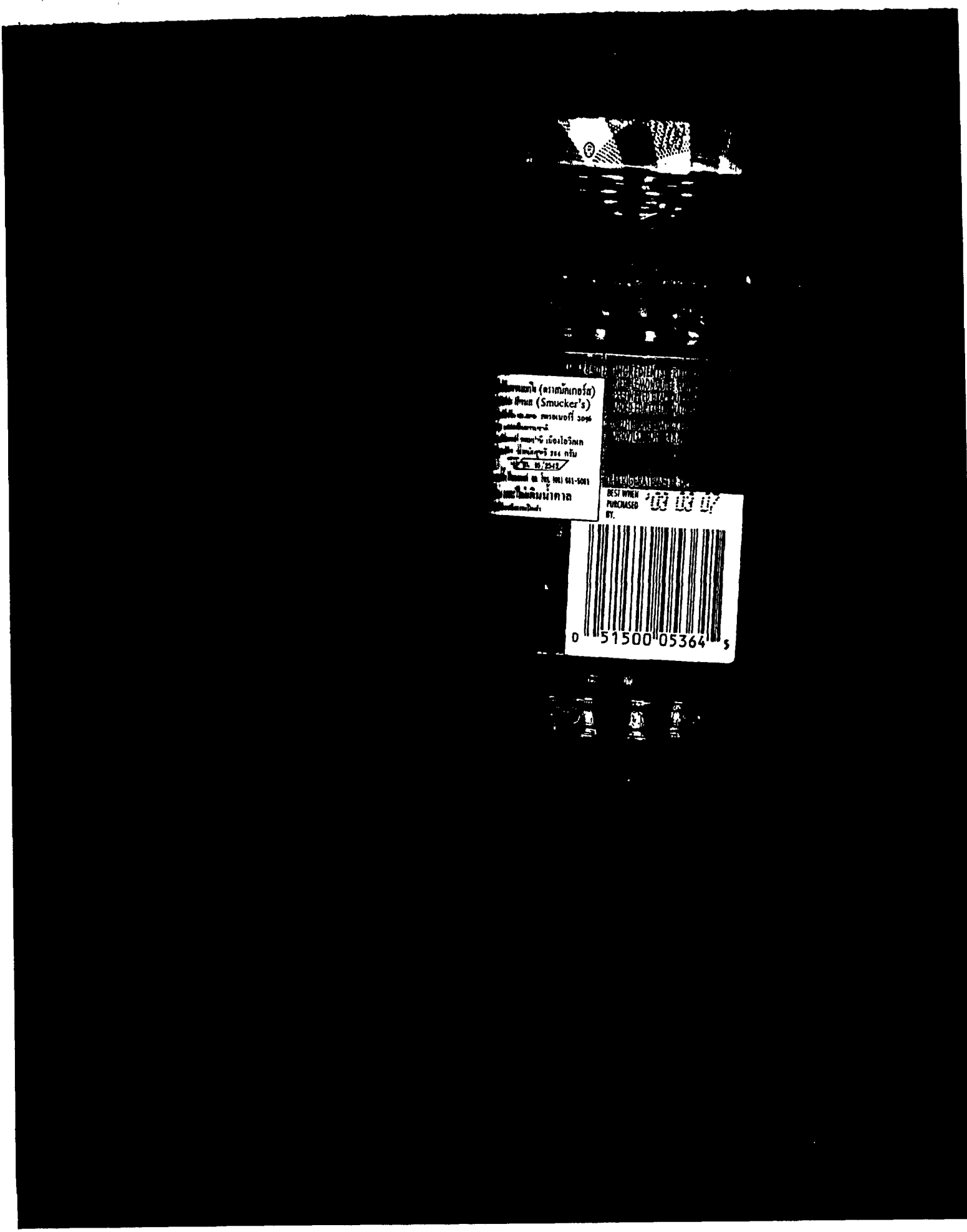
Attachment 2




สตรอเบอรี่ ผลิตภัณฑ์สำหรับทาขนมปัง (ตราสมัคเกอร์ส)
Strawberry Spreadable Fruit (Smucker's)
ไม่ใช้วัตถุกันเสีย และไม่เติมน้ำตาล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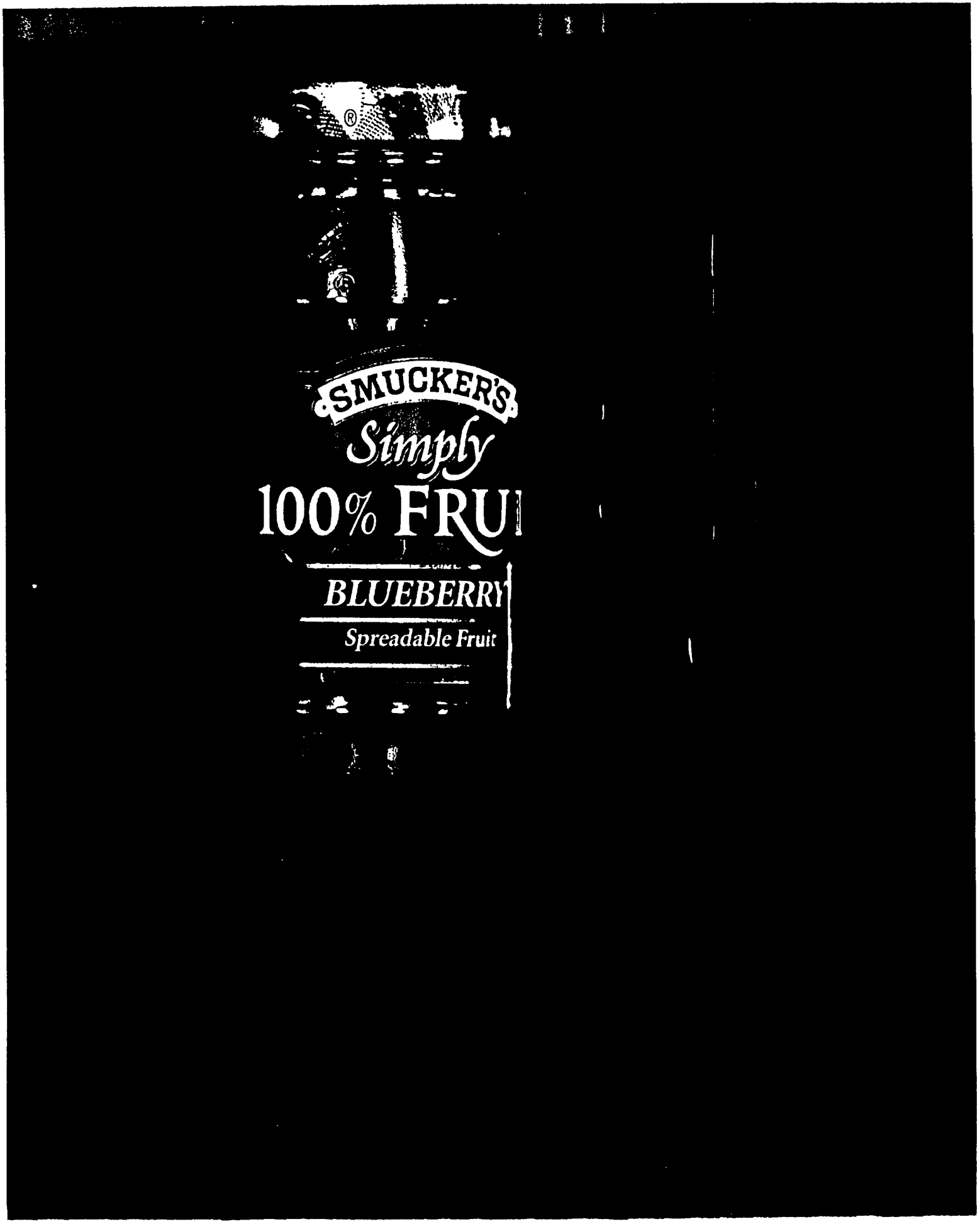
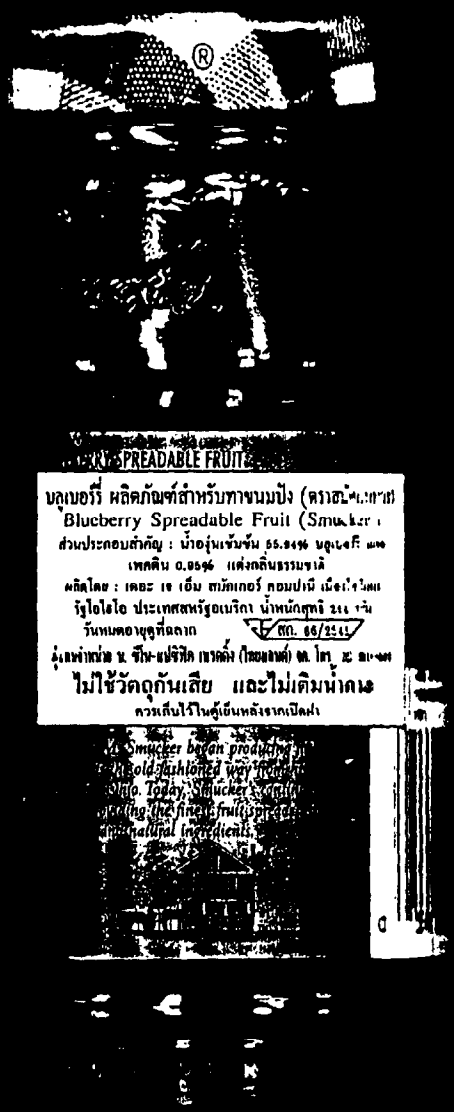
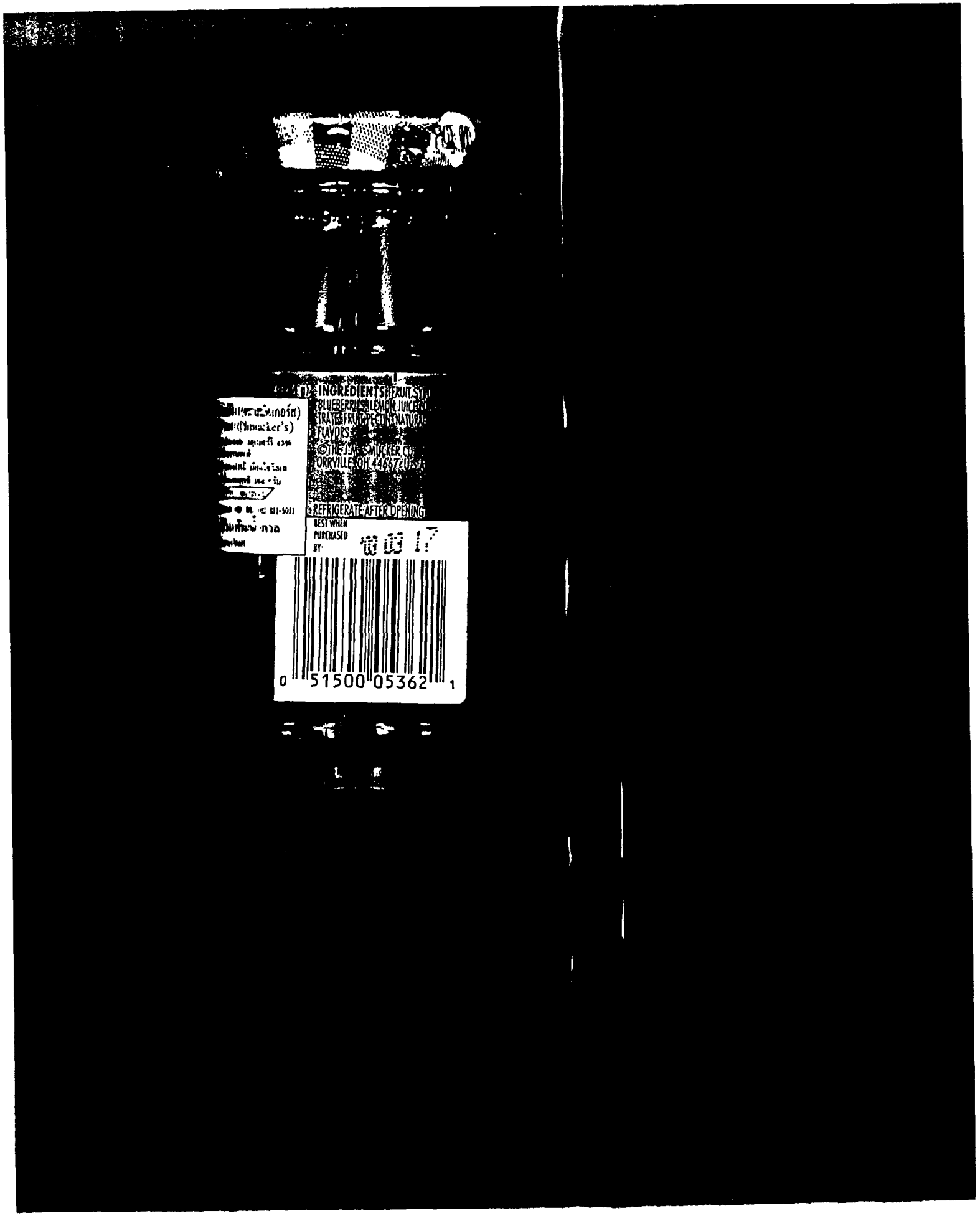
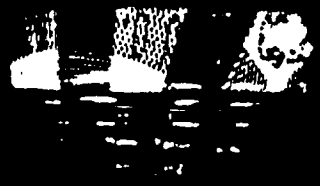

SMUCKER'S
Simply
100% FRU
BLUEBERRY
Spreadable Fruit

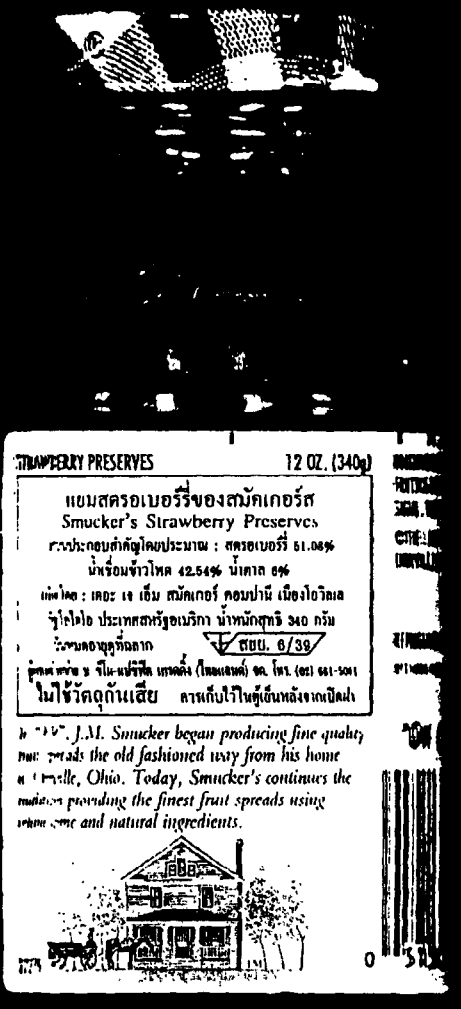

SPREADABLE FRUIT
บลูเบอร์รี่ ผลิตภัณฑ์สำหรับทาขนมปัง (ตราสมัคเกอร์)
Blueberry Spreadable Fruit (Smucker's)
ส่วนประกอบสำคัญ : น้ำองุ่นเข้มข้น 55.94% บลูเบอร์รี่ 44%
เพคติน 0.86% แต่งกลิ่นธรรมชาติ
ผลิตโดย : เดอะ เจ เอ็ม สมัคเกอร์ คอมปานี เมืองออร์เรนจ์
รัฐโอไฮโอ ประเทศสหรัฐอเมริกา น้ำหนักสุทธิ 454 กรัม
วันหมดอายุที่ฉลาก
ผลิตก่อน 06/2544
ผู้แทนจำหน่าย บริษัท เนชั่นแนล เทรดดิ้ง (ไทยแลนด์) จำกัด
ไม่ใช้วัตถุกันเสีย และไม่เติมน้ำตาล
ควรเก็บไว้ในตู้เย็นหลังจากเปิดฝา
Smucker began producing
old-fashioned way
Today, Smucker's
the finest fruit
natural ingredients.

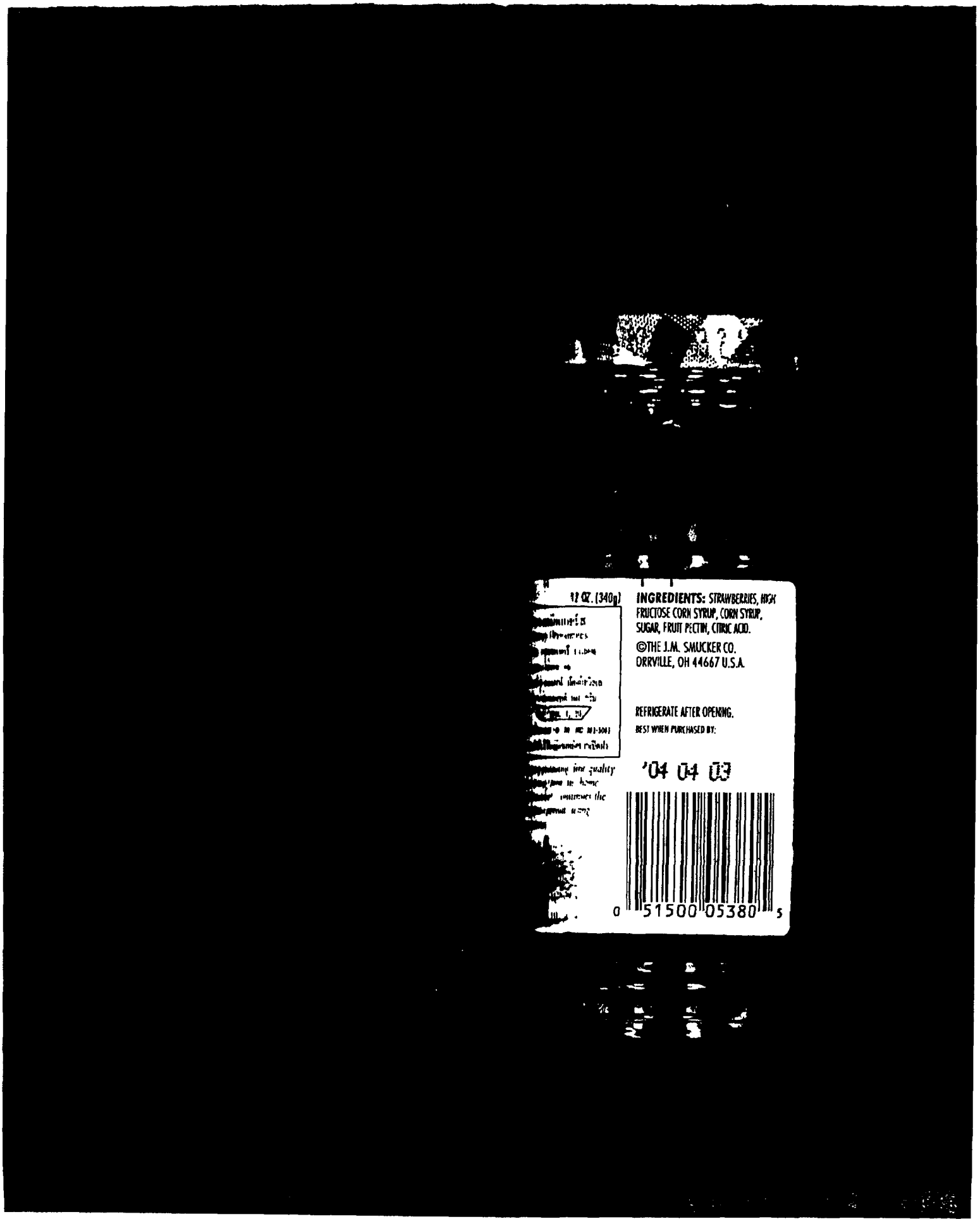

INGREDIENTS:
REFRIGERATE AFTER OPENING
BEST WHEN PURCHASED BY:
0 51500 05362 1

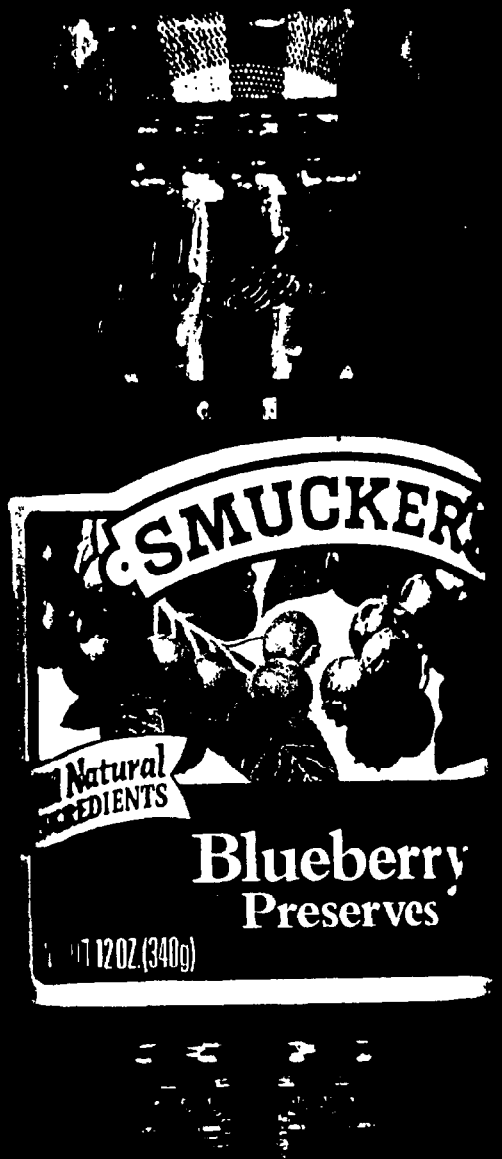


SMUCKER'S

Strawberry
Preserves


STRAWBERRY PRESERVES
12 OZ. (340g)
แยมสตรอเบอร์รี่ของสมัคเกอร์ส
Smucker's Strawberry Preserves
ส่วนประกอบที่สำคัญโดยประมาณ : สตรอเบอร์รี่ 61.08%
น้ำเชื่อมข้าวโพด 42.54% น้ำตาล 6%
ผลิตโดย : เดอะ เจ เอ็ม สมัคเกอร์ คอมปานี เมืองไอวิลเล
รัฐโอไฮโอ ประเทศสหรัฐอเมริกา น้ำหนักสุทธิ 340 กรัม
ดีที่สุด ก่อน 6/39
ในไว้วัดดูก้นเสีย
J.M. Smucker began producing fine quality
fruit spreads the old fashioned way from his home
Orrville, Ohio. Today, Smucker's continues the
tradition providing the finest fruit spreads using
wholesome and natural ingredients.


12 OZ. (340g)
INGREDIENTS: STRAWBERRIES, HIGH FRUCTOSE CORN SYRUP, CORN SYRUP, SUGAR, FRUIT PECTIN, CITRIC ACID.
©THE J.M. SMUCKER CO.
ORRVILLE, OH 44667 U.S.A.
REFRIGERATE AFTER OPENING.
BEST WHEN PURCHASED BY:
'04 04 03
0 51500 05380 5


SMUCKER'S
Natural
INGREDIENTS
Blueberry
Preserves
NET 12 OZ. (340g)

BLUEBERRY PRESERVES 12 OZ. (340g)

แยมบลูเบอร์รี่ของสมัคเกอร์ส

Smucker's Blueberry Preserves

ส่วนประกอบสำคัญโดยประมาณ : บลูเบอร์รี่ 50.03%

น้ำเชื่อมข้าวโพด 49.56% เพกติน 0.29%

ผลิตโดย : เดอะ เจ เอ็ม สมัคเกอร์ คอมปานี เมืองไอร์เวง

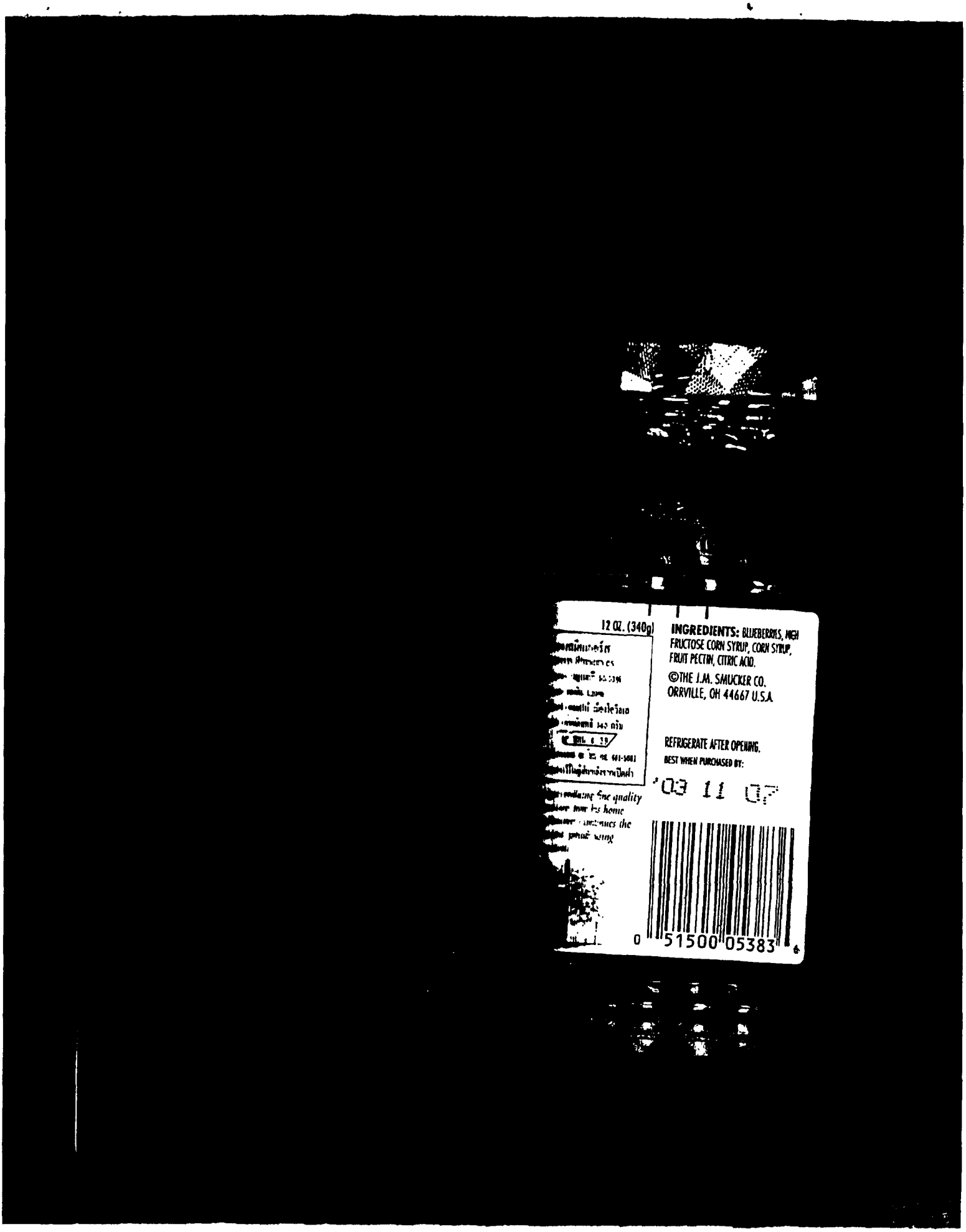
รัฐโอไฮโอ ประเทศสหรัฐอเมริกา น้ำหนักสุทธิ 340 กรัม

วันหมดอายุที่ดีกว่า สบย. 4/39

ผู้แทนจำหน่าย บ. ซีน-อปซิคัล (ประเทศไทย) จก. โทร. (02) 411-xxxx

ไม่ใช้วัตถุกันเสีย ควรเก็บไว้ในตู้เย็นหลังจากเปิด

In 1897, J.M. Smucker began producing fine quality fruit spreads the old fashioned way from his home in Orrville, Ohio. Today, Smucker's continues the tradition providing the finest fruit spreads using wholesome and natural ingredients.


12 OZ. (340g)
INGREDIENTS: BLUEBERRIES, HIGH FRUCTOSE CORN SYRUP, CORN SYRUP, FRUIT PECTIN, CITRIC ACID.
©THE J.M. SMUCKER CO.
ORRVILLE, OH 44667 U.S.A.
REFRIGERATE AFTER OPENING.
BEST WHEN PURCHASED BY:
'03 11 07
0 51500 05383 6