

**A STUDY IN HYPE AND RISK:
THE MARKETING OF SKIN BLEACHES**

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NEW YORK STATE DEPARTMENT OF CONSUMER AFFAIRS

A report by the
City of New York
Department of Consumer Affairs

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- Helps keep skin clear and clean!



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I. SUMMARY

In 1990, hundreds of thousands of U.S. consumers -- mostly African-Americans -- bought some \$44 million worth of over-the-counter skin bleaches containing hydroquinone (HQ) as the active ingredient. Because of serious concerns that skin bleaches can lead to a disfiguring skin disease and may be carcinogenic, the Department of Consumer Affairs is asking the U.S. Food and Drug Administration to ban HQ-based skin bleaches until all safety concerns have been resolved. But since these products are also blatantly mislabeled, we are asking the FDA to immediately seize and order removal, under Sec. 304 of the federal Food, Drug and Cosmetic Act (FDCA), of all HQ-based skin bleaches now on store shelves.

A ban is justified because a 1989 study¹ by the National Toxicology Program, U.S. Department of Health and Human Services, indicated that HQ might be carcinogenic. Other studies, performed in the U.S. and South Africa, link HQ to a skin condition, exogenous ochronosis, with symptoms of dark blue-black spots. Citing this disease, South Africa banned over-the-counter sale of skin bleach in 1990.

Skin bleach makers are also flaunting both the federal Fair Packaging and Labeling Act (FPLA) and the Food Drug and Cosmetic Act (FDCA). Specifically, a Consumer Affairs review of eleven skin bleach products found they misrepresent themselves as able to "even skin tone," "brighten" the complexion, and "remove pimples," and they urge their use to "moisturize" the skin or as "a make-up base." In fact, the proper use of skin bleach is limited to merely lightening certain darker areas of the skin. Bleaches very rarely work to "even" skin tone or "brighten" the overall complexion. Skin bleaches must also be used with a sunscreen -- which is often not included in the bleach -- or else the skin may redarken, a material fact that bleach packaging usually fails to disclose. Skin bleach packages also never warn of the risk of exogenous ochronosis and, in fact, encourage the prolonged and liberal use of this product, which may exacerbate this skin condition.

Last year, the FDA seized "Fresh Choice" orange juice simply because, by incorrectly using the word "fresh" in its name, it was "misbranded." The regular misbranding of skin bleaches similarly justifies a seizure.

¹ *Toxicology and Carcinogenesis Studies of Hydroquinone in F344/N Rats and B6C3F1 Mice (Gavage Studies).*

Recognizing that skin bleach marketing is a special problem and that a drug-specific regulation would provide the industry with needed uniform disclosure standards, the FDA in 1978 began the lengthy administrative process of issuing a comprehensive regulation governing skin bleach labeling. The regulation would require specific package language for warnings, directions for use and certain product limitations. But soon after taking office, the Reagan Administration killed many important proposed FDA regulations, including the FDA's attempt to limit skin bleach marketing abuses.

The FDA's decade-plus failure to enforce the Fair Packaging and Labeling Act, the Food, Drug and Cosmetic Act, and its delay in finalizing the labeling regulations, has allowed hundreds of millions of dollars worth of skin bleach cream to be sold under false pretenses or for purposes for which they were never intended. Our survey found the following false or misleading claims still on the shelves:

- Artra Skin Tone Cream recommends its use as a "daily foundation cream or as a perfect night cream." Not a good idea. Skin bleach is supposed to be used only on very limited spots.
- Dr. Fred Palmer's Skin Whitener's box says, "for a lighter, brighter complexion." Direct violation of the FDCA and the proposed regulations.
- Porcelana's box says, "evens out skin tones." The FDA's proposed regulations would directly prohibit claims of making skin "even."
- Venus de Milo's box says it "gives a lighter, smoother complexion." Another violation.

The FDA was finally set to issue the long-delayed labeling regulation this month. But another hitch has developed: the FDA is concerned about a 1989 safety study which suggested that hydroquinone, the active ingredient in all over-the-counter skin bleaches, could be carcinogenic. According to FDA staff we spoke with last month, final implementation of the regulation may be delayed because of this study.² President Bush's announcement in

² Previously, an FDA staff member told us the rules had not yet been finalized because of a "question of priorities," indicating that finalization of the skin bleach cream regulation was a low priority in comparison with other concerns. (11/18/91 conversation with Michael Kennedy, Chief of the Monograph Policy Coordination and Information Division, OTC Drug Evaluation.) A few weeks later, Mr. Kennedy told us that the final rule issuance has not been postponed, only "delayed." We learned about the 1989 study of possible carcinogenic effects from Michael Benson, Pharmacist, Monograph Policy Coordination and Information Division, on 12/30/91.

his State of the Union Address of a 90-day moratorium on all new regulations makes it more likely that final action on the skin bleach packaging measure will be delayed at least until Spring. Appendix A provides the details of how far each product still needs to go to comply with the proposed labeling requirements.

Instead of merely promulgating the proposed regulations, the Department of Consumer Affairs urges the FDA to seize this product, followed by a ban on all HQ-based skin bleaches. If future studies unequivocally prove that HQ is safe, the ban can be lifted. However, existing studies indicate that, for now, the prudent ethic is -- safety first.

II. THE PROBLEM WITH SKIN BLEACHES

For decades, consumers have used skin bleach agents (usually a "skin bleach cream") in hopes of lightening the overall complexion, producing an even skin tone, banishing freckles, and making scars disappear. In the United States, \$44 million dollars worth of bleach creams were sold in 1990.³ Blacks purchase most skin creams, although no reliable breakdown of purchase by race could be obtained.⁴

Hydroquinone, at 2% strength, is the only active ingredient for skin lightening currently permitted in over-the-counter drugs.⁵ According to an FDA panel of experts, HQ works by "lightening limited areas of brownish skin", through "suppression

³ 1990 figures from AC Neilson. Sales of bleach creams from January 1991 to August 1991 totaled \$30,278,000. The numbers reflect total sales from food stores, mass merchandisers and drug stores.

⁴ In letters responding to the FDA's Proposed Rules for skin bleach creams, makers of these products, including Norcliff Thayer, Plough Inc., Nicholas Products, and Carson Products often described the racial identity of their consumers as black. One 1982 letter from the lawyers for Nicholas Products stated that black consumers purchase over 50% of bleach products (11/1/82 letter of Kleinfeld, Kaplan and Becker to FDA Dockets Management Branch, obtained through the Freedom of Information Act).

⁵ At one time, mercury was also used as a skin bleach, but in 1990 the FDA determined that mercury is not safe or effective for this purpose. See "Skin Bleaching Products For Over-The-Counter Human Use Establishment of a Monograph," *Federal Register*, 11/3/78, p. 51553.

However, the FDA did not ban the use of mercury as a skin bleach agent until 11/7/90, effective on 5/7/91. See, "Status of Certain OTC Drug Category 2 and 3 Active Ingredients Final Rule," *Federal Register*, 11/7/90, pps. 46917-46919.

Higher concentrations of hydroquinone are available by prescription.

Another form of HQ used to bleach the skin, Monobenzyl Ether Hydroquinone (MBE), is also available by prescription. MBE was first tested for use as a skin lightener when it became evident in 1939 that black workers in a tannery developed lightened skin when exposed to MBE in their gloves. But when tests of MBE were performed in 1953, it was found that the "depigmenting ability was unpredictable", causing "irritation, sensitization, and leukoderma". See: Kenneth A. Arndt, "Topical Use of Hydroquinone as a Depigmenting Agent" *Journal of the American Medical Association*, 11/65, pps. 965-967.

of melanin pigment formation within the skin cells."⁶ In other words, it interrupts the process by which skin produces its color.

We reviewed eleven different skin bleach cream products made by eight companies: Medicis Corp.'s Esoterica Regular and Esoterica Sunscreen; J. Strickland Co.'s Artra Skin Tone Cream; Dr. Fred Palmer Ultra Blend and Tone and Dr. Fred Palmer Skin Whitener, both made by Carson Products; Ambi Skin Tone Cream, made by Kiwi Brands; Palmer's Skin Success, manufactured by E.T. Browne Drug Co.; Porcelana Medicated Fade Cream and Porcelana Medicated Fade Cream Sunscreen Formula, made by Dep Corporation; Venus de Milo Complexion Cream, which is imported from Nigeria; and Shirley Skin Litener Cream, made in Taiwan by Shirley Chemical Corp.

We found that many of these products directly contravene the findings of the 1978 FDA Advisory Panel on Over-the-Counter Miscellaneous External Drug Products. The FDA used this panel's report to draft the proposed regulations, which first appeared in the *Federal Register* on November 3, 1978. After inviting and receiving public comments on the proposed regulations on September 3, 1982, the FDA issued a Tentative Final Monograph,⁷ with an invitation for final written public comments by November 3, 1982. The FDA then failed to enact the proposed regulations.

The proposed regulations would prescribe label language that would lead skin bleach manufacturers to comply with the Food, Drug and Cosmetics Act requirements to disclose on packaging the proper purposes and uses of skin bleach creams.

The regulations are aimed at basically four areas.

- First, skin bleaches should not be used to "even" skin tone, as most manufacturers suggest, because they tend to be applied somewhat indiscriminately and they do not have a selective action on only certain areas. Half the skin bleaches we reviewed come in large-mouthed, tub containers, encouraging users to apply the product "indiscriminately." Narrow-mouthed tubes would make it easier to apply very small amounts only to limited areas of hyper-pigmentation.

- Second, while they do lighten limited areas of darker skin

⁶ "Skin Bleaching Drug Products for Over-The-Counter Human Use, Tentative Final Monograph," *Federal Register*, 47 No. 172, 9/3/82, p. 39108. For a more technical discussion of how hydroquinone works, see Kathryn B. Penney, "Depigmenting Action of Hydroquinone Depends on Disruption of Fundamental Cell Processes," *The Journal of Investigative Dermatology*, 82 No. 4 (1984), pp. 308-310.

⁷ U.S. Food and Drug Administration, "Skin Bleaching Drug Products for Over-the Counter Human Use; Tentative Final Monograph."

or discoloration, skin bleach creams should not be used as overall complexion lighteners, moisturizers or make-up bases. But putting skin bleaches in tub containers clearly associates them with cold creams and non-bleach moisturizers. They should also not be used in attempts to "whiten" or "lighten" the entire complexion, as a few manufacturers openly suggest.

- Third, they should be used only in conjunction with a sunscreen or sunblock with a Sun Protection Factor of at least 20; half the skin bleaches we reviewed do not contain either. All but one of those that do have sun protection fail to disclose its strength.

- Fourth, the proposed FDA regulations require packaging to say that skin bleaches do not work on very dark skin; this disclosure is rarely made, and two manufacturers even feature dark-skinned models on packages and in advertisements.

More specifically, here is a comparison of what the FDA's proposed regulations call for and what we found on store shelves.

A. Manufacturers should not claim that skin bleaches will make skin color "even."

We found major skin bleach products identifying themselves as products to "even" and "smooth out" skin tone. This clearly violates the proposed regulations, specifically:

Statements that refer to making the skin color 'even' are not acceptable because they imply that skin bleaching agents have a selective action on concentrations of pigment and would produce even color if applied indiscriminately to wide areas of skin.⁸

Nonetheless:

- Palmer's Skin Success labels say it can "even" skin tone.
- Artra Skin Tone Cream packages say the product "blends areas of uneven skin color."
- An advertisement⁹ making similar claims for Palmer's Skin Success Cream says "nothing smoothes out skin tone more

⁸ Federal Register, 9/3/82 p. 39111.

⁹Copies of ads are attached as Appendix B.

evenly."¹⁰

- An advertisement for Posner Creme de Tone says the product will "even tone in just one step."¹¹

- An advertisement for Esoterica is headlined, "It makes your skin just one shade."¹² The Esoterica package promises to "fade and prevent age spots, freckles, and other skin discolorations, and even skin tone."

Dr. James Nordlund, a pigment-cell biologist at the University of Cincinnati and an expert on hydroquinone, agrees with the FDA's finding that bleach creams cannot produce an even skin tone. In an interview he said: "Although the marketing for these products make this claim [that bleach cream products can even skin tone] this was not the reason these products were designed. The products were developed to treat specific areas of excessive pigmentation. When I see patients, I tell them to apply the bleach to hyper-pigmented areas, not just smear it all over...the products are really ineffectual in achieving this goal".¹³

But that's what many of the package instructions say to do. Artra Skin Tone Cream, for example, recommends use as a "daily foundation cream or as a perfect night cream." And that's what the large-mouth tub containers of Esoterica, Procelana, Dr. Fred Palmer, and Palmer's Skin Success encourage; consumers almost unavoidably will take a sizeable quantity on their fingers and spread it over their skin.

Why are skin bleach manufacturers so eagerly marketing their products, not as skin bleaches, but as skin tone eveners? One likely answer: African-Americans are feeling increasingly uncomfortable with the idea of whitening their skin, yet manufacturers still want to sell the same HQ product in the 1990s that they advertised in the 1940s and 1950s as a skin whitener. Manufacturers have noticed that the term "skin color toning" is now much less offensive to black consumers than the term "bleach".¹⁴ When the FDA proposed that skin bleaches should be

¹⁰ *Essence*, May 1991.

¹¹ *Ebony*, September 1991.

¹² *Essence*, February 1992, p. 15.

¹³ Telephone interview, 11/1/91.

¹⁴ In 1979, Nicholas Products asked 85 African-American women to choose the least offensive of the following terms: "skin bleaching cream," "skin lightener cream," "skin color toning cream," "skin cream which lightens dark pigment to produce an even toned appearance." 55% said that "skin color toning" was least offensive. 45% said that "skin bleaching" was most offensive. Letter from Kleinfeld, Kaplan, and

identified only as a "skin bleach agent," or "skin lightener,"¹⁵ manufacturers protested, arguing that other terms, such as those which described the ability to "even-tone" the skin, were more appropriate.¹⁶

This switch from marketing skin bleach as a whitener or brightener is seen in advertisements for bleach creams in recent issues of *Ebony* and *Essence* magazines, which no longer claim to give "lighter, brighter skin." Instead, bleaches promise to moisturize, fade spots, and produce an even-toned skin.

Carson Products is marketing both the old and the new way by selling skin bleach with the same HQ concentration under two different labels. One Carson product, "Dr. Fred Palmer Skin Whitener," claims to fade spots and "lighten and brighten" the complexion. The other product, "Dr. Fred Palmer Blend and Tone," claims to fade spots and produce a "more even complexion," implying that the product will lighten selectively only those areas of the skin that are darker and produce a skin tone that matches the lighter areas. Label directions for the former merely say the "whitener" can be used on the complexion, while the "blend and tone" label says it can be used as a "makeup base." But the FDA says that HQ will lighten all the skin it comes in contact with, further lightening the lighter areas as well as the darker areas -- raising serious questions about exactly how the blending will occur.

The word "tone" is often used on labels and in ads right after the word "even." The FDA preferred that the word "tone" not be used in conjunction with skin bleach products. As the FDA put it, "the word 'tone' has a number of meanings, two of which are apt to be confused when applied to products for use on the skin: 'color quality or value' and 'healthy elasticity.' The agency believes that substantial confusion can be prevented by excluding the word 'tone' from labeling of a skin bleaching drug product."¹⁷

Becker, 2/1/79 to the FDA.

¹⁵ *Federal Register*, 9/2/82, p. 39117.

¹⁶ Several companies suggested other terms for the product besides "skin bleach agent," such as "skin cream," "skin cream which lightens," "medicated skin cream," "skin tone treatment." But the FDA maintained that the terms "skin bleaching," and "skin lightener" best describe the action of the cream, and were terms consumers were familiar with. *Federal Register*, 9/3/82, p. 39111.

¹⁷ *Federal Register*, 9/3/82 p. 39111

B. Labels and package inserts should clearly communicate skin bleach's sole function -- to lighten limited spots.

What, exactly, can skin bleach creams do? Can they impart an overall "lighter and brighter complexion," as most manufacturers claimed when marketing them in the 1950s and as Carson Products still claims? Not really. Lightening the entire complexion with HQ is impractical. It would be necessary to buy very large amounts of this product and apply it all over the skin for extended periods and still, when use was discontinued, the skin would redarken.

Dr. James Nordlund, a researcher at the University of Cincinnati, says of hydroquinone, "The product was not designed to lighten the complexion. Hydroquinone has a minimum probability of lightening dark skin. Theoretically, if you took a half pound of bleach, and smeared it all over your body, you could lighten the skin color. But it simply doesn't work very well. In practice, it is an unsubstantiated, silly claim."

Thus, while the FDA's proposed regulations would require skin bleaches to describe themselves as a skin "lightener" or "skin bleach agent," the FDA did not imply that they could be used for an extended period, all over the skin, in order to lighten the entire complexion. Indeed, the FDA proposed rules limit the description of what bleach products should be used for as follows:

(Select one of the following: For the gradual fading of "or Lightens") "dark (brownish)" (select one of the following: "discolorations," "pigment," "spots," "blotches," or "areas") "in the skin such as (select one of the following: "freckles," "age and liver spots," or "pigment in the skin that may occur in pregnancy or from the use of oral contraceptives.")¹⁸

And the rules would require this limiting direction:

Adults: apply a small amount as a thin layer on the affected area twice daily, or use as directed by a doctor.

In other words, their use should be confined to very limited areas -- the "affected area." The entire complexion can hardly be considered an "affected area." Yet, as Michael Kennedy, Chief of the FDA's Monograph Policy Information Branch, told us, "There's always been a problem in the area of skin bleach -- promoting the product on larger areas of the body and for longer

¹⁸ *Federal Register*, 9/3/82, Sec. 358.80, p. 39117.

periods of time."¹⁹

As pointed out earlier, most skin bleach manufacturers now position their product as a "skin tone evener," perhaps under the belief that some potential users do not want to be reminded that what the product really does is lighten the skin. They also position themselves as moisturizers or make-up bases. For example, the front and back panels of the Ambi Skin Tone Cream Package do not mention that it is a bleach cream, and the side panels refer to the fading action only in very small print. The main panels do announce "normal skin formula with Vitamin E" and its "now softer, silkier feel." At quick glance, it's hard to tell just what this product is supposed to do. Artra Skin Tone Cream's package is similar; the front and back of the package say, "Moisturizing formula with Vitamin E and Aloe" and, only in the smaller print on the side is it revealed that the product is a "gentle lightening formula." The Artra Skin Tone Cream tube instructs consumers to "use [Artra] as a daily foundation cream or as a perfect night cream." And Esoterica's package instructions claim it can be used as a moisturizer as well as a bleach.

Ambi and Artra describe the bleaching effect only in small print on their package side panels. The Ambi package says, "Working with your skin's natural chemistry, the active ingredient in Ambi's skin tone cream gently fades dark spots and evens skin discolorations to restore your skin to a soft, natural, beautifully even tone in 3 to 7 weeks." Artra's side panel says, "Artra Cream is specially developed as a highly effective but gentle lightening formula with a rich complex of natural moisturizing ingredients, including Vitamin E and Aloe."

Here are other examples of ambiguity in these product's purposes:

- Artra's advice to use their product as a "daily foundation cream or as a perfect night cream" may encourage its use as an overall complexion lightener or as a moisturizer or cosmetic; none of these uses were approved in the FDA's proposed regulations. According to Dr. James Nordlund, "The consumer should not use bleach as a moisturizer. If you use [the] bleach on normal areas of skin as a moisturizer, then it will lighten those normal areas of the skin."²⁰
- The Venus de Milo Complexion Cream label ("for a lighter, smoother complexion") instructs consumers to use the cream

¹⁹ Telephone conversation on 1/31/92.

²⁰ Telephone interview, 11/1/91.

"twice daily." It does not say how long this should continue to attain the "complexion you want" -- whether days, months, or years.

With the FDA recommending that use be limited to "affected" areas, advising indiscriminate use of skin bleach creams as moisturizers is urging abuse of the product. If all a consumer wants is to moisturize or apply Vitamin E, they don't need a skin bleach cream; there are plenty of HQ-free products to do that.

But the danger of the vague and suggestive package language is that consumers who purchase these products may not realize that they are buying skin bleach and could misuse these products as moisturizers or make-up bases. This is certainly encouraged by the open-mouth, tub design of some product packages. Skin bleach marketing ignores the admonition of the FDA's Michael Kennedy, "Skin bleach is a very potent chemical and should not be treated lightly or carelessly."

C. If skin bleaches lack a sunscreen, which is needed to prevent redarkening, this material fact should clearly be revealed and the user advised to apply one.

Research shows that HQ-treated skin will redarken when exposed to the sun. According to one major study, "the Meirowsky effect (long wavelengths of ultraviolet light, darkening melanin already present in the skin) may be a significant factor in reducing the effectiveness of hydroquinone depigmentation." This study's author advised skin bleach users to apply sunscreen and wear protective clothing.²¹

Some of the skin bleach creams we reviewed do contain a sunscreen, including Ambi, Esoterica With Sunscreen, Porcelana With Sunscreen, Ultra Blend and Tone and Artra Skin Tone Cream. We asked Dr. James Nordlund if the sunscreen contained in skin bleach creams is adequate protection against redarkening. His reply:

The sunscreens only protect against short-wave sunlight, not long-wave sunlight. I tell patients to get the short- and long-wavelength protection, which is generally not available in the skin bleach creams... since the sunscreen is usually inadequate, it's a waste of money. Consumers should buy the bleach and the sunscreen separately, because the companies usually charge extra for bleach products containing the sunscreen.

²¹ Dr. Malcolm C. Spencer, *Journal of the American Medical Association*, 11/29/65, pp. 962-964.

Nordlund recommends a Sunscreen Protection Factor (SPF) of at least 20, a sunblock, or Photoplex, a brand of sunscreen that provides protection against both long and short waves. But only one of the skin bleaches we reviewed, Esoterica With Sunscreen, indicated its SPF -- and it is only "10."

Other skin bleaches -- like Esoterica Regular and Venus de Milo -- apparently do not contain any sunscreen, or at least their packages don't mention any. Porcelana Original is the only one without a sunscreen to advise use of a sunscreen, but this warning is barely visible at the bottom of an insert inside the package. A few contain cautions about exposure to sunlight, such as the suggestion inside the Dr. Fred Palmer's Skin Whitener package to "avoid overexposure to sunlight" to "prevent a return of uneven coloration."

D. Skin bleach packaging should warn consumers that, in the FDA's words, "the lightening effect of (skin bleach) product(s) may not be noticeable when used on very dark skin."

Ignoring this direct FDA admonition, manufacturers market skin bleaches without this warning to dark-skinned women, as seen by the pictures of darker women on many packages and ads we reviewed. Ambi Skin Tone Cream and Artra Skin Tone Cream, for example, have pictures of dark-skinned women on the principal display panels. And Porcelana implies that the product works well on dark-skinned people when it says, "For people with dark skin, continued use of Porcelana helps even-out overall skin tone -- for clear, beautiful skin that stays that way." Only Palmer's Skin Success carries the caveat that it may not work on dark skin.

The results of a major study support the FDA's finding that HQ's effect may not be seen on dark skin. Researchers found that, "only in the lighter Negro skin was it possible to observe any contrast between the hydroquinone treated hand and the control."²²

HQ is less likely to work on darker-skinned blacks for the same reason that it does not work on some spots in people of all races and colors: HQ works only on spots in the epidermis, the outermost layer of the skin. It does not work on spots caused by color in the dermis, which is a deeper layer of skin. According to Dr. Nordlund, darker-skinned people have more color in the dermis than other people.

²² Malcolm C. Spencer, "Topical Use of Hydroquinone for Depigmentation," *Journal of the American Medical Association*, 11/9/65, pp. 962-964.

A Consumer Affairs staff member asked a representative of Plough Inc., manufacturer of Artra Skin Tone Cream, if Artra works on all skin colors. She was assured that it does, and that it is an "ethnic product." When asked what she meant by "ethnic product," she said that the product is for blacks, and that "Caucasians" can't use it. We told her that blacks come in all colors, from dark skin to very light skin, and asked her to be specific about what she meant by "blacks." She replied that the product was designed for people with dark skin.²³

Of all eleven skin bleach product labels we reviewed, the label of only one, Palmer's Success, revealed that the "lightening effect may not be noticeable on very dark skin."

E. Skin bleaches should tell users they are not effective on certain blemishes.

Contrary to some claims, skin bleaches are not effective on blemishes such as moles, stretch marks and pimples. We found that only two brands, Esoterica and Porcelana, openly disclosed these limitations. On a leaflet inserted in the package for Esoterica, consumers are told that the product will not "remove birthmarks, scars or discolorations resulting from disease." An insert in the Porcelana package states that it will "not remove scars or birthmarks."

Advertisements for most bleach creams suggest they can help produce a flawless complexion.²⁴ Dr. Fred Palmer Skin Whitener label openly states that the product helps "ease removal of blackheads."

F. Directions should be explicit.

1. Duration of Use

Many of the bleach products we reviewed gave vague and conflicting directions for how long they should be used. The FDA recommends that skin bleach labels state that "if no improvement is seen after 3 months of treatment, use of this product should be discontinued." Of the skin bleach products DCA reviewed, only Ambi Skin Tone Cream and Palmer's Skin Success carried this warning.

²³ Telephone interview, 11/24/91.

²⁴ An ad for Palmer's Success says "nothing smoothes out skin tone more evenly or fades dark spots more invisibly than Palmer's Success Fade Cream." (*Essence*, May 1991). An ad for Porcelana Cream has a picture of a black woman with a flawless complexion, and the caption reads: "How a naturally beautiful complexion gets that way" (*Essence*, July 1991).

Sometimes, directions can contradict themselves, or be overly optimistic. For example, the Ambi Skin Tone package claims it will "restore" the consumer's skin to a "beautifully even tone in 3 to 7 weeks." But the FDA never said that skin bleach will show results in only three to seven weeks, and Dr. James Nordlund says that three to seven weeks is an unusually short time to fade a spot:

When I'm working with a patient, I tell them that this may take six months to achieve, but we won't use the same product for six months. If the hydroquinone does not work, then we move on. A reasonable period of time to use the hydroquinone is three to four months, as the FDA has indicated. On the other hand, three to seven weeks (given by Ambi), is an unusually short period of time to see a response from the creams. On the average, the patient will notice a change in three to four months. After four months, I would stop use. If there is a partial response, then I would continue up until six months.²⁵

On the other hand, Nordlund said that skin bleaches should not be used indefinitely: "I would not advise the patient to use the product every day, indefinitely. We don't have any studies that have been conducted on long-term, indefinite use."²⁶

2. Safety Precautions

Much of the safety information recommended in the FDA proposed rules is omitted or watered down on bleach labels. Labels are supposed to say that consumers should see a doctor if there is severe irritation. But most skin bleach creams do not even mention that consumers can get an irritation, much less suggest seeing a doctor. One product, Dr. Fred Palmer Skin Whitener, sows confusion by suggesting on the package insert that use be discontinued if irritation develops, but softens this advice elsewhere in the insert by saying, "If skin at any time is made uncomfortable by the use of this cream, discontinue **temporarily**." [Emphasis added.]

²⁵ Interview on 11/1/91.

²⁶ Telephone interview, 11/1/91.

III. HOW SAFE ARE SKIN BLEACH CREAMS?

There is significant medical evidence that hydroquinone may not be safe. A 1989 study, *Toxicology and Carcinogenesis Studies of Hydroquinone in F344/N Rats and B6C3F1 Mice (Gavage Studies)*, by the National Toxicology Program, U.S. Department of Health and Human Services, on the toxicity and carcinogenesis of HQ, found some evidence of carcinogenic activity for rats and mice given HQ by gavage.²⁷ The report's Summary of Peer Review Comments pertinently included the following statement: "Dr. [Franklin E.] Mirer noted that dermal absorption had been observed in preliminary animal studies, a finding of importance for drawing public health conclusions."

The FDA now appears to be postponing the finalization of its HQ regulations from February 1992. Finalization is considered very "unlikely" in February, according to staff we spoke with,²⁸ and the likelihood of finalization is now being made even more remote by President George Bush's recent announcement of a 90-day new regulation moratorium.

Apart from whether HQ can be carcinogenic is the issue of exogenous ochronosis -- dark skin marks or a "blue-black sooty pigmentation in the skin"²⁹ from HQ use. Since the FDA last reviewed the medical literature for safety and efficacy in 1978, there have been several reports in American medical journals linking over-the-counter skin bleach creams containing 2%³⁰ HQ to exogenous ochronosis.³¹ Sometimes another

²⁷ "Under the conditions of these 2-year gavage studies, there was some evidence of carcinogenic activity of hydroquinone for male F344/N rats, as shown by marked increases in tubular cell adenomas of the kidney. There was some evidence of carcinogenic activity of hydroquinone for female F344/N rats, as shown by increases in mononuclear cell leukemia. There was no evidence of carcinogenic activity of hydroquinone for male B6C3F1 mice administered 50 or 100 mg/kg in water by gavage. There was some evidence of carcinogenic activity of hydroquinone for female B6C3F1 mice, as shown by increases in hepatocellular neoplasms, mainly adenomas." Dr. Frank Kari, Study Scientist, p.5 of the report.

²⁸ Telephone interview, Michael Benson, Pharmacist, Division of OTC Evaluation Monograph Policy Coordination and Information, 12/30/91 and 1/27/92.

²⁹ As described by Dayna G. Diven in, "Hydroquinone-Induced Localized Exogenous Ochronosis Treated with Dermabrasion and CO2 Laser," *Journal of Dermatologic Surgery and Oncology*, November 1990, pps. 1018-1022.

³⁰ The FDA's decision to limit over-the-counter bleach creams to 2% HQ concentration was based on a report published in 1975 on the safety of hydroquinone in South Africa. Marianne N. O'Donoghue, "Ochronosis due to Hydroquinone, Letter to the Editor," *Journal of the American Academy of Dermatology* 8 (January 1983) p.123. O'Donoghue, and others on the FDA panel reviewed bleach creams for the "Establishment of a Monograph," *Federal Register* November 3, 1978. To evaluate the safety of hydroquinone, they reviewed the 1975 report by Dr. Findlay, the *British Journal of Dermatology*, which studied cases of

condition, known as colloid millium, may develop. People with this condition have skin that appears to be "spotted with caviar."³²

A near-epidemic of exogenous ochronosis occurred in South Africa in 1979, and resulted in the banning in 1983 of HQ concentrations in excess of 2% plus the requirement that skin bleaches contain a sunscreen with an SPF of at least five. Then, a 1988 study by a South African doctor, N. Hardwick,³³ found that the 2% restriction was still not effective, since people using HQ-based products were still developing exogenous ochronosis, and it was possible for people to still find skin bleaches with a more than 2% HQ concentration. He concluded that "the fact that individuals who had only used skin lighteners since 1983 also developed ochronosis, shows that the 1983 modifications were not adequate...It is possible that any system delivering hydroquinone to the melanocytes will, in time, have its proposed effect on the nearby dermal fibroblasts leading to ochronosis." He concluded, "Hydroquinone has a valid place in dermatological therapy, e.g. for chloasma, but it should be available by prescription."

Thus, in 1990, all HQ preparations were banned in South Africa, except by physician's prescription.

How prevalent is exogenous ochronosis in the United States? The number of cases caused by over-the-counter bleach creams at 2% HQ are unknown, but a few doctors who have reported exogenous ochronosis in their patients have expressed concerns about the safety of hydroquinone at 2%. A 1987 report explained:

Bleaching creams containing hydroquinone are widely used by black individuals in an attempt to "brighten" or lighten the complexion. Although these products may be effective initially at lightening the skin, with

exogenous ochronosis in black South Africans who used bleach creams that contained high doses of hydroquinone. The panel determined that concentrations of hydroquinone at no more than 2% is safe.

³¹ A few of the cases reported in medical journals include: Kris Howard, "Exogenous Ochronosis in a Mexican-American Woman," *Cutis*, March 1990, Thomas Conner, "Hyperpigmentation Following Use of Bleach Creams," *Archives of Dermatology*, January 1987, p. 105-110; Diven, *Journal of Dermatologic Surgery and Oncology*, November 1990, p. 1018-1021; and Naomi Lawrence, "Exogenous Ochronosis in the United States," *Journal of the American Academy of Dermatology*, May 1988, p.1207-1209.

³² G.H. Findlay, "Exogenous Ochronosis and Pigmented Colloid Milium from Hydroquinone Bleaching Creams," *British Journal of Dermatology* 93 (March 1975) p. 613-622.

³³ N. Hardwick, "Exogenous Ochronosis: An Epidemiological Study", *British Journal of Dermatology* 120 (1989) p. 229-238.

long-term use, they may cause hyperpigmentation. Patients frequently react to the hyperpigmentation by increasing the frequency of application of the bleaching agents, which only worsens the condition.³⁴

Dr. David Cullison reported a 1983 case of exogenous ochronosis of a 58-year-old black woman who used over-the-counter bleach cream containing 2% HQ to "brighten" her complexion. When her face began to darken, the patient increased the number of daily applications on her face from two to six times in the hopes of lightening her skin.³⁵ Another case, reported in May 1988, involved a black woman, age 62, who used 1% HQ bleach cream for two to three years to remove a dark area on her cheek. Her cheek lightened after she used it for a few months, then she noticed the color darkening.³⁶ Safety depends to a large extent on "the amount, frequency, and vigor of application," according to Dr. Cullison.³⁷

In a letter to the FDA from Professor R. Summers, head of the School of Pharmacy, Medical University of South Africa, to the FDA on December 1988, Dr. Summers questioned whether even 2% or less HQ concentrations are safe:

Since the tentative [FDA 1982] monograph was published however, a number of papers have appeared in the literature which indicate that the allowed concentrations of hydroquinone are not safe...in view of these papers and a number of others which describe leucoderma as a consequence of the use of skin bleaching preparations, would it not now be advisable to reconsider the whole monograph, more especially the use of hydroquinone as the active ingredient? ³⁸

³⁴ Connor, *Archives of Dermatology*, January 1987.

³⁵ David Cullison, "Localized Exogenous Ochronosis", *Journal of the American Academy of Dermatology*, June 1983, pp.882-889.

³⁶ Lawrence, *Journal of the American Academy of Dermatology*, May 1988, p.1207.

³⁷ Cullison, *Journal of the American Academy of Dermatology*, June 1983, p. 888.

³⁸ Letter to Food and Drug Administration Dockets Management Branch, 12/15/88, Professor R.S. Summers, Head: School of Pharmacy, Medical University of Southern Africa. The following documents, and notes on the implications of the study were cited: 1. Howshaw R A, Zimmerman K G Menter A, 1985, "Ochronosis-like pigmentation from hydroquinone bleaching creams in American Blacks." *Archives of Dermatology*, 121, p. 105-108. This paper implicates 2% hydroquinone-containing preparations. 2. Phillips J. I.; Isaacson, C. and Carmen H., 1986, "Ochronosis in Black South Africans who used skin lighteners," *American Journal of Dermatology*, 8., p. 14-21. 3. Tidman M. J.; Horton, J. J.; MacDonald, D. M., 1986, "Hydroquinone- induced ochronosis-light and electron-microscopic features." *Clinical Exp Dermatology*, 11, p. 224-228. This paper implicates a 2% hydroquinone-containing product. 4. Lawrence N.; Bligard C. A.;

Cases of exogenous ochronosis are likely under-reported. Consumer Affairs staff who asked a customer representative of Carson Products about using Dr. Fred Palmer Skin Whitener to "lighten and brighten" the complexion were told that the product would not be safe to use on a long-term basis, because consumers who have used the product in this manner have gotten "irreversible spots" on their faces. Nonetheless, Carson's product contains no warnings. Furthermore, the "Skin Whitener" label encourages consumers to use the product as a complexion lightener in the very manner the customer service representative warned against.

Can higher than 2% concentrations of HQ be found in the United States? There have been reports of creams that have in excess of 7% hydroquinone being available over the counter.³⁹

IV. WHY BLEACH AT ALL?

A glance at skin bleach advertisements in black-oriented magazines of the 1950s illustrate what HQ-based products have traditionally been used for -- to lighten the skin. Old skin bleach ads in *Ebony*⁴⁰, without exception, told black readers that the bleach creams could produce "lighter and brighter" skin, thereby reinforcing the attitude that the dark skin of blacks is not desirable. Two ads were especially blatant: an ad for Black and White Bleaching Cream invited *Ebony* readers to "see your dull, dark drab skin take on a new lighter, brighter, smoother look".⁴¹ An ad for Nadinola Bleaching Cream had a picture of a

Reed R.; Perret W. J.; 1988, "Exogenous Ochronosis in the United States," Journal of American Academy of Dermatology, 18, p. 1207-1211. The two cases cited both implicate 2% hydroquinone-containing preparations.

³⁹ Dr. Earle W. Brauer, MD., of the Revlon Research Center in Edison, NJ, wrote a letter in *Archives of Dermatology* 121 (October 1985), p. 1239, in which he stated: "Manufacturers may consider it prudent but not obligatory to follow FDA guidelines. Chemical assays of these OTC products have disclosed variation in quantity, even to an excess of 7%."

⁴⁰ "Be Lovely, Be Loved with Lighter Brighter Skin," Black and White Bleaching Cream Advertisement, *Ebony*, November 1957 p. 128.

"Lighter Looking Skin in Just 7 Days or Money Back," Mercolized Wax Cream, *Ebony*, February 1958, p. 82.

"Now--New Golden Peacock Creme Turns Skin Shades Lighter," Golden Peacock Creme, *Ebony*, December 1957, p. 86.

"Remove that Mask of Dull, Dark Skin and Give Romance a Chance!" Nadinola Bleaching Cream, *Ebony* November 1957, p. 14.

⁴¹ *Ebony*, November 1957, pg. 128.

smiling light-skinned woman with a frowning dark mask in her hands. The text read, "Remove That Mask of dull, dark skin and give romance a chance!"⁴²

Negative attitudes towards black skin color in these ads mirrored a broader racism in society. Quite frankly, bleach creams were used by blacks who wanted to change their color, since a darker color often relegated them to a lesser economic and social status. As noted writer Charles Johnson observed, many blacks of earlier generations⁴³ were concerned with

... 'brightening the race' through careful marriage, the terrible importance of fair skin, curly hair, and 'yellah women'. They were not fools, these old folks, they knew what they experienced and understood skin-bleaching creams and straightening combs as important because these changed their stained 'outsides' by which, in this social system, the depth of their 'insides' would be gauged by others.⁴⁴

By the mid-1970s, however, black consumer attitudes towards bleach creams had changed. As mentioned earlier when discussing the trend to marketing skin bleaches as able to "even" skin tone, bleach cream manufacturers noted that most blacks no longer wanted to use skin bleach creams to actually lighten the complexion. One manufacturer, Plough Inc., makers of Artra Skin Tone cream, said in a 1979 letter to the FDA:

Particularly, black users of these products do not desire bleaching of the skin, but rather lightening of hyper-pigmented areas. Implications of a whitening or bleaching effect imparts a negative and possibly misleading connotation."⁴⁵

⁴² *Ebony*, November 1957, pg. 14.

⁴³ An article in the November 1991 issue (pp. 57-58) of *Essence* magazine by Michel Marriott, "COLORSTRUCK," raises questions about whether negative attitudes towards dark-skinned women still exist in today's generation of youth. The article cites media watchers who observe the prevalence of light-skinned black women, and the scarcity of dark-skinned women, in movies, music videos, and advertisements. Other experts quoted in the article argued that the reason light-skinned women are more privileged than dark, is because of Eurocentric values that are still prevalent in this society.

The observation that lighter skin is preferred over dark in the media was confirmed by the July 1991 study done by the NYC Consumer Affairs Department, "Invisible People: The Depiction of Minorities in Magazine Advertisements."

⁴⁴ Charles Johnson, *Being and Race: Black Writing Since 1970* Bloomington: Indiana University Press, 1988, p. 27.

⁴⁵ February 1, 1979 letter to Office of Hearing Clerk, FDA from Plough Inc. Docket Number 78N-0065.

Consequently, as this report has illustrated, very little skin bleach advertising now promotes skin-lightening, and instead talks more about even skin tone.

V. IMPORTED SKIN BLEACHES -- A SPECIAL PROBLEM

The FDA has permitted two skin bleach products, Shirley Skin Litener Cream, and Venus de Milo, manufactured by unidentified foreign companies and bearing vague claims on the labels, to be imported and sold in the United States. Although the manufacturers of over-the-counter and prescription drugs are required by law to list their products in the Import Drug Products files of the Food and Drug Administration, neither of these products, nor the companies, were so listed.

Moreover, Venus de Milo does not list the name of the manufacturer, the U.S. representative, or the U.S. distributor on its packaging.⁴⁶ Although the name of the manufacturer of Shirley Skin Litener is provided on the package, neither the company nor the U.S. distributor or representative is listed with the Import Drug Products file.⁴⁷

Both Shirley Skin Litener and Venus de Milo labels make rather dubious claims including:

- The Shirley label states that the product "removes pimples." This claim falls outside the FDA's definition of how bleach creams should be used and for what use they are effective. The label also implies that bleaching will help make the skin "clear and healthy." According to the FDA (1978 report), this claim is "unsupported by scientific data".⁴⁸
- The Shirley Cream product label also claims it has "extra strength." Does this mean that it contains more than 2% of the active ingredient hydroquinone, the maximum amount allowed by the law? If so, the product is illegal; if not, it is misleading because it is no stronger than other skin bleach creams.

⁴⁶ *Requirements of Laws and Regulations Enforced by the U.S. Food and Drug Administration U.S. Department of Health and Human Services* p. 44. For imported products, the "legal requirements that must be met are the same for imported and domestic products, the enforcement procedures are necessarily different. Imported products regulated by the Food and Drug Administration are subject to inspection at the time of entry through U.S. Customs. Shipments found not to comply with the laws and regulations are subject to detention." (p.2)

⁴⁷ Telephone conversation, Flora Chang, Consumer Safety Officer, Drug Listing Branch, Food and Drug Administration, 1/6/92.

⁴⁸ *Federal Register*, p. 51553.

• Venus de Milo Complexion Cream deceptively claims to be "fast acting." The 1978 FDA report denounced the claim "fast acting," because it is a "claim which impl[ies]y an immediate rather than a gradual skin bleaching effect through use of certain terms ...fast-acting, quick, and prompt."⁴⁹

VI. SEIZE AND BAN

Skin bleaching creams are subject to the jurisdiction of the Food and Drug Administration under the Food, Drug and Cosmetic Act (FDCA),⁵⁰ which covers products that affect the chemical structure and function of skin cells -- which is what hydroquinone does. The FDCA prohibits the "misbranding" of drugs:

If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual."⁵¹

A prosecution clearly can be commenced for misbranding a drug based on labeling or advertising even if there are no specific regulations, such as the ones the FDA has proposed for skin bleaching creams to require specific language on skin bleach packaging. Failure to mention that redarkening will occur when bleach application is stopped, failure to disclose that bleaches do not work on very dark skin, and marketing bleaches as a make-up base or moisturizer are all examples of "misbranding." They are "material" facts about the consequences of using skin bleaches.

A prosecution may also be brought under Section 1453 of the

⁴⁹ *Federal Register*, November 3, 1978, p. 51554.

⁵⁰ 21 U.S.C.A. Sec. 301-392.

⁵¹ 21 U.S.C.A. Sec. 321(n).

Fair Packaging and Labeling Act (FPLA). This Act establishes general requirements for the location and contents of drug labeling and packaging. Specific FPLA regulations under Title 21 of the Code of Federal Regulations cover drug labeling.

Seizure of misbranded foods and drugs is provided for under Sec. 304(a) of the FDCA, to wit:

(1) Any article of food, drug, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce or while held for sale (whether or not the first sale) after shipment in interstate commerce...shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States...

We urge the FDA to invoke this section against HQ-based skin bleaches.

The Consumer Affairs Department would have brought actions against all of the skin bleach manufacturers for violation of the New York City Consumer Protection Law's prohibition of unfair trade practices and deceptive advertising, were it not for federal enforcement pre-emption in the FPLA and the FDCA. Even had DCA been authorized to proceed against deceptive labels and ads, this Agency could not have ordered removal of the product from the shelves. That's the FDA's job.

Appendix A

This appendix compares actual skin bleach labels with proposed labeling standards of the Food and Drug Administration (Tentative Final Monograph), as published in the Federal Register on September 3, 1982.

PROPOSED RULE (a). STATEMENT OF IDENTITY. The labeling of the product contains the established name of the drug, if any, and identifies the product as a "skin bleaching agent," "skin lightener," "skin bleaching (insert dosage form, e.g., cream, lotion, or ointment)," or "skin lightening (insert dosage form, e.g. cream, lotion, or ointment)."

Esoterica (Regular). *Not in compliance.* The product is identified as a "medicated fade cream."

Esoterica (Sunscreen Formula). *Not in compliance.* The product is identified as a "medicated fade cream."

Artra. *Not in compliance.* The product is identified as a "skin tone cream."

Dr. Fred Palmer (Ultra Blend and Tone Cream). *Not in compliance.* The product is identified as "blend and tone."

Dr. Fred Palmer (Skin Whitener). *Not in compliance.* The product is identified as a "skin whitener tone and bleach cream."

Ambi (Skin Tone Cream). *Not in compliance.* The product is identified as a "skin tone cream."

Palmer's Skin Success (Fade Cream). *Not in compliance.* The product is identified as a "fade cream."

Porcelana (original). *Not in compliance.* The product is identified as a "medicated fade cream."

Porcelana (sunscreen). *Not in compliance.* The product is identified as a "medicated fade cream."

Venus de Milo (Complexion Cream). *Not in compliance.* The product is identified as a "complexion cream."

Shirley (Skin Litener Cream). *In compliance.* The product is identified as a "skin litener cream."

PROPOSED RULE (b). INDICATIONS. The labeling of the product contains a statement under the heading, "Indications," that is limited to the following phrases:

(1) For products containing the ingredient identified in 358.10¹ or any combination identified in 358.20.² select one of the following: "For the gradual fading of" (or "lightens") "dark (brownish)" (select one of the following: "discolorations," "pigment," "spots," "blotches," or "areas") "in the skin such as" (select one or more of the following: "freckles," "age and liver spots," or "pigment in the skin that may occur in pregnancy or from the use of oral contraceptives.")

(2) For products containing the ingredient in 358.20., "Contains a sunscreen to help prevent darkening from reoccurring."

Esoterica. Not in compliance with section b (1). The labelling does not contain the heading "Indications." Directions on the label describing uses for the product do not replicate those in the FDA proposed rule. The principal display panel says, "helps fade and prevent... age spots, freckles, and other skin discolorations." The back of the box says, "...designed to help fade and prevent age spots, freckles and other skin discolorations on hands, body and face caused by age, oral contraceptives, pregnancy or overexposure to sunlight." The back of the jar says, "...help gradually lighten skin discolorations." On package inserts, it says, "In addition to help fading spots, Esoterica Cream also works well on fading freckles and larger dark patches and blotches, which are sometimes caused by pregnancy or use of oral contraceptives. Furthermore, Esoterica Cream also helps even out skin tones to keep your skin clearer and younger-looking. (Esoterica, however, will not remove birthmarks, scars or discolorations resulting from disease.)" *Section b(2) does not apply to Esoterica*, since it contains no sunscreen.

Esoterica (Sunscreen). Not in compliance with section b(1). Same reason as for regular Esoterica. *Not in compliance with section b (2).* The labeling does not replicate the proposed rule. Instead, the back of the package says, "Because the sun can aggravate and even cause dark spots and other skin discolorations, Sunscreen Formula Protection Factor of 10."

Artra. Not in compliance with section b (1). The label does not contain the heading "indications." Directions on labelling describing use of the product do not replicate those in the FDA proposed rule. The side of the box says, "gradually fades dark spots and blends areas of uneven skin color. So you achieve the radiant, even tone you desire." The back of the tube says, "Artra cream fades dark spots and areas of uneven skin color, so you achieve the beautiful, even-toned look you want." *Not in compliance with section b (2).* Directions do not replicate proposed rule. Side of box says, "Artra contains protective sunscreens to help prevent recurrence of darkening caused by exposure to the sun's harmful rays."

Dr. Fred Palmer (Ultra Blend and Tone). Not in compliance with section b (1). Does not contain the heading "Indications." Directions on labelling do not replicate the FDA proposed rule. The back of the package says, "...Helps fade age spots, freckles, brown spots and skin discolorations..." The back of the product says, "A fine blend of ingredients to create a more even complexion. An effective aid to

¹ 358.10 Skin bleaching active ingredient. The active ingredient and its concentration in the product is as follows: hydroquinone 1.5 to 2.0 percent.

² 358.20 Permitted combinations of active ingredients. Hydroquinone identified in 358.10 may be combined with any generally recognized safe and effective sunscreen active ingredient identified in 352.10 provided that the product is labeled according to 358.50.

help fade blemishes for a clear and beautiful look." The package insert says, "Used regularly for 6 to 12 weeks Ultra Blend and Tone Cream will help fade unwanted brown spots and blend them to the more natural tones of your skin." Another page of the package insert says, "A truly marvelous skin softener that effectively fades age spots, brown spots, and freckles." *Not in compliance with section b (2).* Top of the box merely says, "with protective sunscreen..." Package insert says, "...protective sunscreen helps darkening from reoccurring."

Dr. Fred Palmer (Skin Whitener). *Not in compliance with section b (1).* Does not contain the heading "Indications." The top of the box says, "for a lighter, brighter, complexion." The back of the product says, "...works to produce a clearer, lighter, brighter complexion. Helps fade skin discolorations and ease removal of blackheads. On the package insert, it says, "...used regularly for 6 to 12 weeks, Dr. Fred Palmer Skin Whitener will help fade unwanted brown spots and blend them to the more natural tone of your skin." *Section b (2) does not apply* to Dr. Fred Palmer (Skin Whitener) the product does not contain sunscreen.

Ambi. *Not in compliance with section b (1).* Directions do not replicate FDA proposed rule. Does not contain the heading "indications." The side of the box says, "cream gently fades dark spots and evens skin discolorations..." *Not in compliance with section b (2).* Directions do not replicate FDA proposed rule since side of box says, "Ambi contains a protective sunscreen to guard against redarkening..."

Palmer's Skin Success. *Not in compliance with section b (1).* Directions do not replicate FDA proposed rule because back of box says, "For the gradual fading of age spots, liver spots, freckles and melasma (the mask of pregnancy, a condition of the skin that may also result from the use of oral contraceptives). Lightens dark pigment in the skin." Note: on the principal display panel it says, "fades dark spots...age spots. Evens skin tone." *Label is in compliance with section b (2).* On the back it says, "Contains a sunscreen to help prevent darkening from reoccurring."

Porcelana (original). *Not in compliance with section b (1).* The principal display panel says, "helps eliminate skin discolorations, age spots, and freckles." The back of the box says, "Porcelana evens out skin tones. Helps lighten skin discolorations and freckles caused by age, pregnancy, oral contraceptives or overexposure to the sun." The back of the product also says, "helps lighten skin discolorations and freckles caused by age, pregnancy, oral contraceptives or overexposure to the sun," and the front of the product says, "helps eliminate skin discolorations, age spots and freckles." On the package inserts, it says, "Porcelana helps fade most skin discoloration problems. From age spots and freckles caused by overexposure to the sun to the dark patches caused by pregnancy or oral contraceptives...(Porcelana, ...will not remove scars or birthmarks). For people with dark skin, continued use of Porcelana helps even-out overall skin tone - for clear, beautiful skin that stays that way." *Section b(2) is not applicable,* since Porcelana original does not contain a sunscreen.

Porcelana (sunscreen). *Not in compliance with Section b(1).* Directions do not replicate FDA proposed rule. The principal display panel says, "helps eliminate skin discolorations, age spots, and freckles." The back of the box says, "Porcelana evens out skin tones. Helps lighten skin discolorations and freckles caused by age, pregnancy, oral contraceptives or overexposure to the sun." The back of the product also says, "Helps lighten skin discolorations and freckles caused by age, pregnancy, oral contraceptives or overexposure to the sun." The package insert says, "Porcelana helps fade most skin discoloration problems. From age spots and freckles caused by overexposure to the sun to the dark patches caused by pregnancy or oral contraceptives... (Porcelana...will not remove scars or birthmarks.)" For people with dark skin, continued use of Porcelana helps even-out overall skin tone-for clear, beautiful skin that stays that way." *Section b(2) is complied with.* On the back of the package, it says, "Contains a protective sunscreen to help prevent darkening from recurring."

Venus de Milo (Complexion Cream). *Not in compliance with section b(1).* Does not have the heading, "indications." Directions do not replicate the proposed rule: One side of the package says, "Hydroquinone gives a lighter, smoother complexion." Another side reads, "A non-greasy vanishing cream with all of these benefits* removes pimples and spots *brightens the complexion..." On the package insert, it says, "...contains that remarkable hydroquinone for added toning to your skin...will also help to clear skin blemishes and achieve that perfect smooth complexion you desire."
Not in compliance with section b (2). Contains no information on sunscreen.

Shirley Skin Litener Cream. *Not in compliance with section b(1).* Does not have the heading, "indications." Does not replicate the language contained in the proposed rule: The side of the package says, "lightens, brightens, softens, smooths." The back says, "hydroquinone brightens and lightens the skin, Allantoin softens and smooths the skin, keeps it clear and healthy." Not in compliance with section b (2), contains no information on sunscreen.

PROPOSED RULE (c). WARNINGS. The labeling of the product contains the following warnings under the heading "Warnings":

(1) For products containing the ingredient identified in 358.10 or any combination identified in 358.20.

(i) "Avoid contact with eyes."

(ii) "Some users of this product may experience a mild skin irritation. If skin irritation becomes severe, stop use and consult a doctor."

(iii) "Do not use on children under 12 years of age unless directed by a doctor."

Esoterica (Regular). Contains the heading, "warnings," on the side of the box, back of the product, and on insert, so *in compliance with section c(1)(i).* *Not in compliance with section c(1)(ii);* on the back of the product, back of the box, and insert it says, "Do not use if skin is irritated. Discontinue if irritation appears." *Not in compliance with section c (1)(iii);* it says on the box, back of product, and insert, "keep out of children's reach."

Esoterica (Sunscreen). *In compliance with section c(1);* contains the heading, "warnings." *In compliance with section c(1)(i);* the back of the package the package insert, and the back of the product says, "Avoid contact with the eyes." *Not in compliance with section c(1)(ii);* instead, the back of the package, the package insert, and the back of the product say, "Do not use if skin is irritated. Discontinue use if irritation appears." *Not in compliance with section c (1)(iii);* it says on the back of the product, the side of the package, and on the package insert, "Keep out of reach of children."

Artra. Contains the heading, "warning" on the side of box, and the back of the product, however, none of the warnings appear under this heading. Instead, the term "caution" is used on the side of the box, and the back of the product. *Not in compliance with section c(1)(i);* on the side of the box, and the back of the product, it says "Keep out of eyes, if contact occurs wash out with water." *Not in compliance with section c(1)(ii);* the side and back of the box product say, "Do not use on irritated or sore skin. If irritation develops discontinue use." *Not in compliance with section c 1 (iii);* side and back of box say, "keep out of reach of children."

Dr. Fred Palmer (Ultra Blend and Tone). *Not in compliance with section c;* does not contain the heading "Warnings." Instead, the side of the box and the package insert contain the heading, "caution." *In compliance with section c(1)(i);* side of box and package insert says, "Avoid contact with eyes." *Not in compliance with section c 1 (ii);* does not replicate language used in the proposed rules because on the side of the box, it says, "If irritation develops, discontinue use." Package insert says, "If irritation

develops, discontinue use and consult a doctor." *Not in compliance with section c(1)(iii)*; side of package and insert says, "Do not use on children under 12 years of age."

Dr. Fred Palmer (Skin Whitener). *Not in compliance with section c*; does not contain the heading "Warnings." Instead, the side of the box and insert say "caution." Labeling is *in compliance with section c(1)(i)*; side of the box and insert say, "Avoid contact with eyes." *Not in compliance with section c 1 (ii)*; box says, "If irritation develops, discontinue use" and insert says, "if irritation develops, discontinue use and consult a doctor." It also says, "If skin at any time is made uncomfortable by the use of this cream, discontinue temporarily." *Not in compliance with section c1(iii)*; the back of the package says, "Do not use on children 12 years of age." The package insert says, "Do not use on children under 12 years of age. Keep this and other medications out of reach of children."

Ambi. *Not in compliance with section c*; does not contain the heading "warnings." Instead, the side of the box and the back of the product say "caution." *The label is in compliance with section c(1)(i)*. The side of the package, and the back of the product say "Avoid contact with the eyes." *In compliance with section c(1)(ii)*. The side of the package and the back of the product say, "Some users may experience mild skin irritation. If irritation becomes severe, stop use and consult a physician." *Not in compliance with section c(1)(iii)*; side of the package and back of product say, "Not recommended for use by children under 12 years of age unless directed by a physician."

Palmer's Skin Success. *In compliance with section c*; does contain the heading "warnings," on the back of the product. *In compliance with sections c(1)(i), c(1)(ii) and c(1)(iii)*.

Porcelana (original). *In compliance with section c*; contains the heading "warnings" on the back of the box and on the package insert. *In compliance with section c1 (i)*; back of the box and the package insert. *Not in compliance with section c 1 (ii)*; the back of the product and the package insert say, "Do not use on broken or irritated skin. If irritation occurs, discontinue use." *Not in compliance with section c(1)(iii)*; back of the product and package insert say, "Not for use on children under 12."

Porcelana (sunscreen). *Same as Porcelana (original)*.

Venus de Milo (Complexion Cream). *Not in compliance with section c*; does not contain the heading, "warnings." *Not in compliance with sections c(1)(i), c(1)(ii), and c(1)(iii)*. On an insert, it says, "Important: Some people are allergic to certain foods, drugs, cosmetics etc., and should irritation appear on the skin then discontinue further use."

Shirley (Skin Litener Cream). *Not in compliance with section c*; does not contain the heading, "warnings." *Not in compliance with sections c(1)(i), c(1)(ii), and c(1)(iii)*; back of product says, "Note: Some people may be allergic to certain foods, drugs, or cosmetics. If any irritation occurs discontinue using the cream."

PROPOSED RULE (d). DIRECTIONS. The labeling of the product contains the following statements under the heading "Directions":

(1) For products containing the ingredient identified in 358.10 or any combination identified in 358.20. "Adults: apply a small amount as a thin layer on the affected area twice daily, or use as directed by a doctor. If no improvement is seen after 3 months of treatment, use of this product should be discontinued. Lightening effect of his product may not be noticeable when used on very dark skin."

"Children under 12 years of age: do not use unless directed by a doctor."

(2) For products containing the ingredient identified in 352.10. "Sun exposure should

be limited by using a sunscreen agent, a sun blocking agent, or protective clothing to cover bleached skin when using and after using this product in order to prevent darkening from reoccurring."

(3) For products containing any combination identified in 358.20. "Sun exposure should be limited by using a sunscreen agent, a sun blocking agent, or protective clothing to cover bleached skin after treatment is completed in order to prevent darkening from reoccurring."

Esoterica (Regular). *In compliance with section d*; does contain the heading, "Directions" on the back of the box and the back of the product. *Not in compliance with section d(1)*; does not contain language that replicates the proposed rule since it says on back of product and box, "Smooth on Esoterica twice a day to help gradually lighten skin discolorations. For maximum results, use Esoterica for at least 6 weeks. Then continue using Esoterica regularly to help prevent skin discolorations from recurring." *Not in compliance with section d(2)*; side of the box and package insert say, "Excessive exposure to the sun should be avoided." *Section d(3) is not applicable*, since Esoterica does not have a sunscreen.

Esoterica (Sunscreen). *In compliance with section d*; does contain the heading, "Directions," on the back of the box and the back of the product. *Not in compliance with section d(1)*; says, "Smooth on Esoterica twice a day to help gradually lighten skin discolorations. For maximum results, use Esoterica for at least 6 weeks. Then continue using Esoterica regularly to help prevent skin discolorations from recurring," on the back of the product and the back of the box. *Section d(2) is not applicable*, since the product contains a sunscreen. *Labeling is not in compliance with Section d(3)*; side of the box and the back of the product say, "Excessive exposure to the sun should be avoided."

Artra. *Complies with section d*; does contain the heading "Directions" on the back of the tube. *Does not comply with section d(1)*; it says, "Cleanse skin thoroughly with a mild cleanser like Artra Beauty Bar. Smooth on Artra until it vanishes. For best results, use Artra 1 to 2 times daily and you will see beautiful results in just a few short weeks. Use Artra as your daily foundation cream or as a perfect night cream." *Section d(2) is not applicable*, since Artra has a sunscreen. *Not in compliance with section d(3)*.

Dr. Fred Palmer, (Ultra Blend and Tone Cream). *Not in compliance with section d*, lacks heading, "Directions." *Does not comply with section d(1)*; package insert says, "Use fingertips to gently and evenly apply a thin layer of cream to the skin. Allow cream to soften skin for one or two minutes: then gently apply a second layer of Ultra Blend and Tone Cream. Blend in until it vanishes. Leave on skin over-night or under makeup. Ultra Blend and Tone Cream should be used once or twice daily, or as desired for full performance...Used regularly for 6 to 12 weeks, Ultra Blend and Tone Cream will help fade unwanted brown spots and blend them to the more natural tones of your skin. With some age spots that are heavy and long lasting, Ultra Blend and Tone Cream will cause gradual fading until the spot becomes light reddish in color. This redness shows the break up of dark pigment and will last only a few days; then will disappear, resulting in an even, well-balanced tone of skin. *Section d(2) is not applicable*, since the product contains a sunscreen. *The labeling does not comply with section d(3)*; package insert says, "To prevent return of uneven coloration, avoid over-exposure to sunlight."

Dr. Fred Palmer (Skin Whitener). *In compliance with section d*; has the heading, "Directions," on the package insert. *Does not comply with section d(1)*; does not contain language that replicates the proposed rule. On the package insert it says, "Use fingertips to gently and evenly apply a thin layer of the cream to the skin. Allow it to soften skin for one or two minutes; then gently apply a second layer of Dr. Fred Palmer Skin Whitener. Leave on skin all night. Remove in the morning or before application of make-up by again washing area thoroughly with a facial soap. Skin Whitener should be

used once or twice daily, or as desired for best results... Used regularly for 6 to 12 weeks, Dr. Fred Palmer Skin Whitener will help fade unwanted brown spots and blend them to the more natural tone of your skin. With age spots that are heavy and long lasting, Dr. Fred Palmer Skin Whitener will cause a gradual fading until the spot becomes light reddish in color. This redness shows the break-up of dark pigment and will last only a few days; then it will disappear, resulting in an even, well-balanced tone of natural skin." *The labeling is not in compliance with section d(2); package insert says, "To prevent a return of uneven coloration, avoid overexposure to sunlight." Section d(3) is not applicable.*

Ambi (Skin Tone Cream). *In compliance with section d;* it has the heading, "Directions" on the back. *Does not comply with Section d(1);* The back of the product says, "Smooth Ambi Cream on face, arms, legs, or anywhere discoloration is a problem. Repeat steps 1 and 2 twice a day, morning and evening. Ambi's toning action is usually visible within 3-7 weeks. If no improvement is seen after 3 months, discontinue use. To maintain your new even-toned skin, use Ambi regularly every morning." *Section d(2) is not applicable;* Ambi contains a sunscreen. *Labeling does not comply with Section d(3);* back of product says, "To prevent darkening reoccurring, limit exposure to sun."

Palmer's Skin Success. *Complies with Section d;* contains the heading, "Directions" on the back. *In compliance with section d(1);* the back says, "Adults: apply a small amount as a thin layer on the affected area twice daily, or use as directed by a doctor. If no improvement is seen after 3 months of treatment, use of this product should be discontinued. Lightening effect of this product may not be noticeable when used on very dark skin. Children under 12 years of age : do not use unless directed by a doctor." *Section d(2) is not applicable;* Palmer's Skin Success has a sunscreen. *Palmer's Skin Success labeling is not in compliance with section d(3);* any reference to this section is not contained on the labeling.

Porcelana: *Complies with section d;* contains a heading, "Directions" on the back of the package, the back of the product, and the package insert. *Not in compliance with section d(1);* on the back of the package and the product, it says, "Include in your morning and evening regimen. Spread Porcelana into darker patches, on face, hands, arms, or body. In six weeks of regular use, you should notice a remarkable difference. Use twice daily to prevent new discolorations from forming..." On the package insert, it says, "Follow these simple steps faithfully morning and night, after getting up and before bedtime. In as little as six weeks you should notice a remarkable difference. (For some people, it may take a little longer.) 1. Twice a day, apply a small amount of Porcelana into darker patches on face, hands, arms, neck, chest, legs. 2. Gently rub in until cream disappears. Close cap tightly after each use." *Not in compliance with Section d(3);* the package insert says, "Avoid overexposure to sunlight. If you do plan to be in the sun, remember to use Porcelana with protective sunscreen. "

Note: The package insert seems to imply that the product works well on very dark skinned people, when it says, "For people with dark skin, continued use of Porcelana helps even-out overall skin tone- for clear, beautiful skin that stays that way." The label does not contain the information required by section d(1), that the product may not work well on very dark-skinned people.

Porcelana (sunscreen). Same as for Porcelana (original), except section d(2). Since this product contains a sunscreen, section (d)2 is applicable, instead of section d(3). Not in compliance with section d(3).

Venus de Milo (complexion cream). *Not in compliance with Section d;* the label does not contain the heading, "Directions." The side of the box and the package insert say, "Wash the skin and gently dry, then apply a small amount of cream by smoothing evenly with the fingertips on the face, neck or arms and legs, etc. Allow the cream to penetrate the skin and after a while apply again, rubbing well in until the cream vanishes. Repeat the application once or twice daily for best results." The label does not say how long to use the product, nor does it caution children, or reveal that it may not work on very dark

skin. *Not in compliance with section d (2)*; the label does not state whether the product contains a sunscreen, and does not advise consumers to use a sunscreen during and after treatment on the affected area.

Shirley Skin Liteer Cream. *In compliance with Section d*; the label contains the heading, "Directions." *Not in compliance with section d(1)*; the label states, "Wash the skin thoroughly in soap and water. Smooth cream on skin until it softens and penetrates, leave for 2 minutes then repeat process. Use twice daily." The product labeling does not say that it may not work on very dark skin. Nor does it say that the product should be discontinued in 3 months if no progress is seen. Children are not advised to avoid use of this product. There is not mention of a sunscreen, and the *labeling does not comply with section d(2)*, which says that a sunscreen should be used during and after application of the bleach on affected areas.

Essence May 1991



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Get even-tone skin,
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The Vitamin
fade cream.
It works like no other,
it is like no other.



Nothing smoothes out skin tone more evenly or fades dark spots more invisibly than Palmer's Skin Success Fade Cream.

Absolutely nothing works the same because Skin Success Fade Cream is the exclusive Fortified Formula — the one with nature's Vitamin E and a Sunscreen to help prevent darkening from reoccurring.

Moisturizing. Soothing. Gentle even on delicate skin. Nothing succeeds like Palmer's Skin Success Fade Cream.

**The effective fading formula
with Vitamin E & Sunscreen
for normal, oily or dry skin.**

Now available in a
convenient
tube.



Science February 1992

ESOTÉRICA

IT MAKES YOUR SKIN JUST ONE SHADE. BEAUTIFUL.



What's beautiful? Even tone skin with an all-over beauty. And you can get that great look with Esotérica.

Esotérica's special formula works deep down, beneath the surface where blotches and darker discolorations form. It gently fades them and in up to

six weeks your skin has a lovelier, more even tone.

Used every morning and night, Esotérica's special moisturizers help prevent ashy dryness.

Day by day you'll see the Esotérica difference. It makes your skin just one shade.

Beautiful.





How a naturally beautiful complexion gets that way.

When you really think about it, a beautiful complexion has very little to do with nature. And everything to do with effort.

It requires moisturizing to smooth away ashy dryness. Gentle cleansing twice a day. Protection from the elements. A healthy face.

And it requires a fade cream as effective as Porcelana[®] medicated.

Unlike other fade creams, Porcelana was made especially for your face. Its recommended by dermatologists to even out dark spots and blemishes with the fastest acting ingredient available. And its light, non-greasy moisturizers help keep your complexion young and smooth.

33% MORE

Porcelana

MEDICATED

ORIGINAL FORMULA

ORIGINAL FORMULA

You only have one face.
Make the most of it with Porcelana.

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**Moisturize
and
even tone
in one
simple step.
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**"Creme de
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BEFORE YOU MAKE UP



DR. FRED PALMER'S

**IN
JUST
7
DAYS
MUST
GIVE
YOU**



LIGHTER, CLEARER Younger Looking Skin

OR MONEY BACK

Yes, in just 7 days be delighted how fast and easy this doctor's formula lightens, brightens and helps clear skin or money back!



**Now Fortified
With Amazing "F.A.T."**

Dr. Fred Palmer's Skin Whitener is double strength. What's more it's fortified with amazing **INC. PHENOL-SULFONATE, "F.A.T."** It lightens, brightens and clears skin fast and at the same time fades blemishes, freckles and off-color spots. Refines enlarged pores. Treats externally caused pimples. Softens blackheads for more easy removal. Makes skin firmer, smoother, younger looking.

**DR. FRED PALMER'S
DOUBLE STRENGTH
SKIN WHITENER**

30c-60c at druggists everywhere
Also Try Dr. FRED PALMER'S
SKIN DELIGHT SOAP . . . 20c



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**LIGHTER,
BRIGHTER SKIN**

Lovely skin draws men like a magnet. Use Black and White Bleaching Cream as directed and see your dull, dark skin take on a lighter, brighter, softer, smoother look. Its bleaching action works inside your skin. Science knows no faster way of lightening skin.

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NOW-- NEW GOLDEN PEACOCK CREME TURNS SKIN SHADES LIGHTER

*Amazing Newly Tested, Soft Substance Starts Whitening
Skin Overnight--fights Oily Skin, Blackhead Bumps*
by Marie Davant

NEW YORK, deadline: Marvellous news for people with dark skin—or skin that is darker in some spots than others! New Golden Peacock Bleach Creme contains an amazing soft substance that fades discolored melanin in dark skin, lightens dark spots.

Dark spots at your hairline, uneven streaks around your nose and mouth, neck, arms are completely blended in the areas around them—leaving your skin one glamorous "even" cream-tone all over... as creamy, fair and lovely as can be.

Laboratory Develops Cream

Famous Peacock Laboratory has mixed this tested ingredient with four other skin whitening elements, for the delightful new Golden Peacock facial cream! Not one—but 5 skin-whitening agents—proved by tests to be absolutely safe and harmless!

No other cream can make dark skin so light and beautiful... make dark spots so creamy and even-looking! Just

one application of this new cosmetic often brings amazing results.

In just 16 days see skin turn shades lighter. In 30 days—fair and smooth... lovely as can be. What's more—new Golden Peacock Bleach Creme will keep it that way!

Start using Golden Peacock right away. Look in your mirror and see a wonderful improvement! Dark skin should be shades fairer. Dark spots should fade. Its creamy new substance Blackhead bumps disappear. Surface pimples dry up—leaving the complexion creamy-white, smooth and lovely.

New Golden Peacock Bleach Creme is made by the famous Peacock Laboratory that has made skin bleaches for over 42 years. If you want a beautiful creamy-white skin—never use substitutes—ask for Golden Peacock Bleach Creme... only \$1 at your drug or cosmetic counter today. Large Imperial size (3 months' supply) in gold box \$2. Or order by mail on money-back guarantee.

CLIP AND MAIL THIS COUPON TODAY!

Golden Peacock, Inc.
Dept. EP-21
Paris, Louisiana
Just for the full money-back guarantee

ORDER NOW!



REMOVE THAT MASK of dull, dark skin and give romance a chance!

It's a shame how often a poor complexion cheats a girl out of fun and affection. To be loved—to be lovely—do as so many beautiful women do. Use NADINOLA Bleaching Cream!

Nothing—no *nothing*—will improve your complexion in so many different ways as NADINOLA. Is your skin dark and dull? NADINOLA will lighten and brighten it. Are you embarrassed by oily shine, enlarged pores and blackheads? Some creams try to cover up these complexion faults. But NADINOLA works *within* the skin to help correct them.

Perhaps your complexion has become sort of tired and old-looking. NADINOLA will give it new freshness, make it look years younger. And many women buy NADINOLA just for their hands—to fade those ugly, speckled brown spots which spoil their beauty.

NADINOLA works so fast that these wonderful results are guaranteed from just one treatment-size jar. So get NADINOLA right away at your favorite cosmetics counter. There are two kinds—one for oily skin, the other for dry skin. Both are guaranteed to satisfy you completely or your money back.

NADINOLA, Paris, Tennessee

NADINOLA

BLEACHING CREAM

Just one jar will make your complexion lighter, brighter and lovelier.



FOR OILY SKIN
This cream is for oily skin. It is non-irritating, non-drying, and non-staining. It is guaranteed to relieve your skin of all oiliness. Price, \$1.25.



FOR DRY SKIN
This cream is for dry skin. It is non-irritating, non-drying, and non-staining. It is guaranteed to relieve your skin of all dryness. Price, \$1.25.

It's so easy to have
**LIGHTER,
BRIGHTER
SKIN**



Just use Black and White Bleaching Cream as directed and see your dull, dark, drab skin take on a new lighter, brighter, softer, smoother look.

Black and White Bleaching Cream's action works inside your skin. Modern science knows no faster way of lightening skin. Buy it today!



Get Black and White Bleaching Cream at all drug counters 45¢, 65¢

BLACK AND WHITE
BLEACHING CREAM

MERCOLIZED WAX CREAM

Guarantees



LIGHTER LOOKING SKIN

*in just 7 days
or money back!*

Take advantage of the amazing Mercolized Wax Cream guarantee. If your skin doesn't look actually lighter after using Mercolized Wax Cream for just one week, your money will be cheerfully refunded. Just smooth fast acting Mercolized Wax Cream on your face each night... for 7 nights. You'll see amazing results almost at once—Mercolized Wax Cream's speedy bleaching action lightens your complexion, fades blotches, spots and freckles, brings excessive skin oiliness under control. This is no cover up cosmetic, Mercolized Wax Cream works *under* the skin surface to bring about these marvelous results. Used by beautiful women for over 40 years. 100% money back guarantee. Trial size only 75c. Buy a jar today.



Your Drug, Department Store
or Cosmetic Counter has it

MERCOLIZED WAX CREAM



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Memorandum

Date

From Director
Division of OTC Drug Evaluation (HFD-210)

Subject Material for Docket No. 78W-0065

To Dockets Management Branch (HFA-305)

- The attached material should be placed on public display under the above referenced Docket No.
- This material should be cross-referenced to Comment Let 1 (2-19-92).


William E. Gilbertson, Pharm. D.

Attachment

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