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August 21, 2001

Ms. Jennie Butler
Documents Management Branch
U.S. Food and Drug Administration
Department of Health and Human Services
Room 1-23, 12420 Parklawn Drive
Rockville, Maryland 20857

Re: Proposed remedial regulations re products containing different ingredients between labeled and label-exempt versions especially relating to fountain diet Coca-Cola and Bottled diet Coca-Cola

Dear Ms. Butler:

As per our conversation last week, I am enclosing for filing the original and two copies of our amended petition on behalf of Mrs. Zapka.

Please let me know if the agency requires anything further.

Very truly yours,

Robert J. Stein III

RJS/cc

cc: Mr. Joseph Mendelson III (Encl.)
Mr. Christopher Murphy (Encl.)

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01P-0190

AMD 1

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

In the Matter of

PROPOSED REMEDIAL REGULATIONS REGARDING Products containing different ingredients between labeled and label-exempt versions especially relating to FOUNTAIN DIET COCA-COLA AND BOTTLED DIET COCA-COLA	)	Docket No. 01P-0190/CP 1

CITIZEN PETITION

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TO: Documents Management Branch
U.S. Food and Drug Administration
Department of Health and Human Services
Room 1-23, 12420 Parklawn Drive
Rockville, Maryland 20857

August 14, 2001

AMENDED CITIZEN PETITION

Judy Zapka, on behalf of herself and all others similarly situated, by her undersigned attorneys, Krislov and Associates, Ltd., herewith submits this amended petition under Sections 201, 402, 403, 409, and 701 of the Federal Food, Drug and Cosmetic Act, petitioning that the Commissioner of Food and Drugs shall issue amended or withdraw FDA regulations as hereinafter identified and specified.

A. SUBJECT MATTER

The subject matter of this petition is proposed remedial regulations regarding products sold under the same brand name, but which contain different ingredients in the non-labeled versions from the ingredients listed in the labeled version. For example, bottled Diet Coca-Cola lists that it is sweetened 100% with aspartame, while Diet Coca-Cola, dispensed in a fountain format, is sweetened

primarily with saccharin. Coca Cola is aware of consumers' confusion and knows that a substantial percentage of consumers would not buy the fountain version if they were aware that it has been sweetened primarily with saccharin. Changes are necessary to the published regulations, and to the labeling of products in order to negate and correct confusion caused by deceptive marketing practices adverse to the consumer. Primarily, it is sought to order Coca-Cola, and all other manufacturers of products whose unlabelled versions' ingredients materially differ from the same branded product, to disclose this to consumers on the labeled product, or otherwise effectively alert consumers to the existence of such differences.

1. This petition is brought against Coca-Cola Company, among others, by petitioners who have consumed Diet Coke® from the fountain ("fountain Diet Coke") and were deceived by the marketing practices employed by Coca-Cola Company ("Coca-Cola") into believing that fountain Diet Coke has not contained saccharin. Coca-Cola markets "Diet Coke" as being a single unified product sweetened exclusively with aspartame, without making any distinction between fountain Diet Coke and Diet Coke in a bottle or can ("bottled Diet Coke").

2. Diet Coke is an excellent example of the problem. While bottled or canned Diet Coke is, in fact, sweetened exclusively with aspartame and so described in its nutritional label, fountain Diet Coke, unlabelled for consumers, has been actually a different product, sweetened instead with a mixture that's predominantly saccharin.

3. **The Petitioners.** Petitioner brings this case on behalf of herself and on behalf of millions of consumers nationwide. Petitioner **Judy Zapka** resides in Willowbrook, Illinois and is conducting an action against Coca-Cola in the United States District Court for the Northern District of Illinois over its deceptive practice. Petitioner and all members of the class were misled by Coca-

Cola's failure to disclose that fountain Diet Coke and bottled Diet Coke are actually different products and that fountain Diet Coke has contained saccharin while bottled Diet Coke does not.

4. The **Coca-Cola Company** has its headquarters and principal place of business in Atlanta, Georgia and is incorporated and exists under the laws of Delaware. Coca-Cola is in the business of manufacturing, producing and dispensing soft drinks and other beverages.

B. ACTION REQUESTED

5. It is petitioned that the FDA Commissioner amend 21 Code of Federal Regulations (21CFR) and issue additional food labeling requirements, which will address consumer confusion and disadvantage that exists when consumer food products, including soft drinks (1) are dispensed or sold in different formats bearing the same brand name; (2) contain different ingredients when dispensed or sold in such formats; and (3) have different labeling requirements for each format under the existing regulations, exempting some from any labeling disclosure of contents, so that (4) consumers buy the product in the exempt format mistakenly believing it to be identical to the labeled product, even though the exempt-format product contains different ingredients, some of which are the subject of consumer health concerns, and (5) concerning which the relevant manufacturer knows of the consumer confusion and that a significant number of consumers would refuse to buy the product if they knew.

6. **Mandatory Labeling Under Existing Regulations.** Title 21 of CFR §101.9(a), provides that nutrition information relating to food shall be provided for all products intended for human consumption and offered for sale unless an exemption is provided for the product in paragraph (j) of such section:

"(1) When food is in package form, the required nutrition labeling information shall

appear on the label in the format specified in [§ 101.9].

"(2) When food is not in package form, the required nutrition labeling information shall be displayed clearly at the point of purchase (*e.g.*, on a counter card, sign, tag affixed to the product, or some other appropriate device). Alternatively, the required information may be placed in a booklet, looseleaf binder, or other appropriate format that is available at the point of purchase."

7. **Exemptions from labeling**. 21 C.F.R. § 101.9(j), entirely exempts certain foods from labeling. As relevant here, § 101.9(j)(2) exempts food products which are: (i) served in restaurants,...; (ii) Served in other establishments in which food is served for immediate human consumption (*e.g.*, institutional food service establishments...); (iii) sold only in such facilities,...; (iv) used only in such facilities, and not served to the consumer in the package in which they are received....

8. Somewhat differently conditioned, 21 C.F.R. § 101.9(j)(2)(v)'s exemption of food products which are sold by a distributor who principally sells food to such facilities, precludes the exemption for foods that are to be manufactured or repackaged into consumer products, or "if there is a reasonable possibility that the product will be purchased directly by consumers." 21 CFR § 101.9(j)(2)(v)(A) and (B).

9. **Reason Why an Amendment to Existing Regulations is Necessary**. Major consumer confusion exists where products contain different ingredients when sold in different formats or packaging. Certain products regularly sold to consumers in one familiar labeled package have different ingredients when sold in label-exempt circumstances. As a result, consumers who examine the labeling of a labeled product generally and reasonably believe that the nutritional disclosures in the labeled product describe identically named label-exempt products. As a result, consumers are misled to believe that the product is one single formulation, but are unknowingly

ingesting certain ingredients which they otherwise would not knowingly consume. Moreover, certain manufacturers, such as Coca-Cola, know of the consumer confusion and intentionally exploit it.

10. **Proposed Clarification to the Regulations**. Elimination of Consumer confusion could be accomplished by several alternative methods. The key is placing consumers on notice that a product with a similar name whose contents or ingredients are disclosed may have seriously different contents or ingredients than a product if sold in another form.

11. Accordingly, one amendment to the labeling requirements could be a mandatory notice on the labels of products whose contents differ when sold in labeled vs. exempt format. As examples: "This label describes the contents in the enclosed package only. The product dispensed in restaurants or other packaging contains different ingredients."

12. Another amendment might be where the ingredients in an exempt format would require specific identification in a labeled format. This would be especially appropriate where there is widespread consumer or medical concern about an ingredient, such as saccharin, that is contained only in the unlabeled format. For example, a product sweetened by aspartame in the labeled product, but by saccharin in an exempt format, could, in order to eliminate confusion with the labeled product, have the following required language on its label. "This nutrition information applies only to this packaging. The product dispensed in restaurants and fountains contains saccharin."

13. **Carcinogenicity and Regulatory Policies**. Many broad-range regulatory issues came to prominence when the Food and Drug Administration proposed in 1977 to ban saccharin from foods, drugs, and cosmetics because of studies in which the sweetener caused cancer in test animals. Questions were raised concerning the desirability of permitting health benefits to be weighed against health risks in judging whether a product should be removed from the food supply, and the extent

to which the government should go in protecting the consumer.

14. **Signs on Saccharin-Containing Foods.** The Saccharin Study and Labeling Act added a provision to the Federal Food, Drug, and Cosmetic Act requiring that a warning appear on the labels of saccharin-containing foods, making any such food not so labeled to be misbranded. For these purposes, "saccharin" includes calcium saccharin, sodium saccharin, and ammonium saccharin. The prescribed label warning was: "USE OF THIS PRODUCT MAY BE HAZARDOUS TO YOUR HEALTH. THIS PRODUCT CONTAINS SACCHARIN WHICH HAS BEEN DETERMINED TO CAUSE CANCER IN LABORATORY ANIMALS."

The warning was required to appear both on the label and in any labeling for a food product.

15. **Signs in Retail Stores and on Vending Machines.** The SSI Act provided that retail stores that offer saccharin-containing foods for sale, but not for immediate consumption, were required to display a notice to consumers regarding the information that is required to appear on the food packages. Foods offered for sale at retail were misbranded if the notice was not present.

16. The Government's heightened concern about the health risks posed to consumers by saccharin was evidenced in 21 U.S.C. § 343(a), which concerned the Secretary of Health as to vending machines (P.L. 106-272, approved 9-22-2000), and which includes the following:

> "The Secretary may by regulation require vending machines through which food containing saccharin is sold to bear a statement of the risks to health which may be presented by the use of saccharin. A regulation under this subsection shall require such statement to be located in a conspicuous place on such vending machine and as proximate as possible to the name of each food containing saccharin which is sold through such machine."

17. In the last weeks before his term ended, former President William Clinton, on December 21, 2001, signed legislation allowing removal of the warning label required since 1977

on saccharin-sweetened foods and beverages.

18. Consumers have received little or no notification of such legislation since the signing thereof and consequently consumer attitudes and views concerning saccharin, purposely built up over a period of many years have understandably remained unchanged, and should remain so indefinitely.

19. In fact, consumer research undertaken by Petitioner showed that after the Department of Health and Human services removed saccharin from its list of suspected carcinogens (May 15, 2000), consumer attitudes towards saccharin in their diet soft drinks remains unchanged.

20. The widespread, prominent use of saccharin warnings over the past decade has created a general consumer awareness that saccharin is a suspected carcinogen. As a result many consumers avoid products containing saccharin. This fact is known to manufacturers such as Coca-Cola and, in fact, in the mid-1980s caused many soft drink manufacturers to change the sweetener profile in their bottled diet products to 100% aspartame.

C. STATEMENT OF GROUNDS

21. The grounds of this petition are very simple, namely that millions of consumers presently have no full disclosure, and are being deliberately misled and manipulated, by manufacturers such as Coca-Cola, to purchase and ingest unlabelled products in the confusion that they have the same ingredients as labeled products bearing the same brand name.

22. Pursuant to 21 CFR § 5.10(a)(1), the Commissioner of Food and Drugs has the authority, derived from the Secretary of Health and Human Services, to promulgate regulations under the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et. seq.*

23. Diet Coca-Cola is an example best known to petitioners and exemplary of the possible harm and market confusion which requires regulatory attention.

24. Prior to November of 1984, Diet Coca-Cola products were sweetened by saccharin or a mixture of aspartame and saccharin. Consumer concerns about ingesting saccharin are substantial, and were (and are still) known by Coca-Cola. Such concerns were propagated by the long-term U.S. government emphasis on health risks associated with saccharin in foods, especially with respect to the dread and too often fatal disease of cancer. The Government's program for limiting or drastically reducing consumer use of saccharin has only cased with President Clinton's signing of legislation on December 21, 2000. Since December 21, 2000, American consumers have received little or no notification of what transpired so recently. Moreover, concerns about the use of saccharin remain widespread throughout the medical and scientific community, and among consumers.

25. **Coca-Cola Facts.** By November of 1984, Coca-Cola knew or believed that millions of consumers would prefer an aspartame sweetened (i.e., non-carcinogenic) soft drink to a saccharin sweetened soft drink because of perceived health risks associated with saccharin. This perception--that saccharin causes cancer--was a major reason for Coca-Cola's decision to switch Diet Coke® to aspartame only and to vigorously advertise and promote the change to 100% aspartame.

26. On November 29, 1984, Coca-Cola announced in a press release that it would "replace the saccharin in Diet Coke® with the sweetener aspartame." The company stated that the reformulated Diet Coke® would be available in some areas of the country within days and throughout the United States by the early part of 1985. It was also stated, at that time, that "for now" the 100% aspartame version of Diet Coke® would not be available at the fountain, leaving it

uncertain whether that meant that Diet Coke® would no longer be available at the fountain, until a conversion had taken place or that the fountain version was and would continue to be saccharin sweetened, or that the fountain version would be chnaged to 100% aspartame at a later date.

In fact, fountain Diet Coke® always was, and continues to be, sweetened predominantly by the undisclosed and reputed carcinogen saccharin.

27. From approximately November, 1984 until sometime in 1992 or 1993, Coca-Cola marketed Diet Coke® highlighting it as a beverage sweetened with NutraSweet®, and prominently displayed the NutraSweet® "pinwheel" (a trademark identifying a product as containing NutraSweet) on bottled Diet Coke containers and in Diet Coke® advertisements.

28. During a period ending sometime in 1993, some of the print advertisements for Diet Coke® typically contained fine print indicating that Diet Coke® with 100% NutraSweet® was still not available at fountains, and some of the televised advertisements flashed a brief subtitle to the same effect, still leaving the meaning uncertain.

Those advertisements, however, never disclosed that the fountain diet product contains the reputed carcinogen saccharin.

29. At approximately the same time that Diet Coke® switched to generic aspartame, it stopped advertising that it contained "NutraSweet". Diet Coke® cans and bottles, however, listed only aspartame as its sweetener, and did not indicate that fountain Diet Coke contained saccharin or even that it was a different product. Diet Coke® advertisements also ceased stating that diet Coke with 100% NutraSweet was not available at the fountain.

30. From sometime in 1992 or 1993 to present, Coca-Cola has misadvertised "Diet Coke®" as a single, unified product. It has omitted in its advertisements, or otherwise generally

informed consumers, that fountain Diet Coke and bottled Diet Coke are actually two different products and that one contains saccharin. Nor has it included in its advertisements that fountain Diet Coke contains saccharin.

31. Thus, the labels of Diet Coke® purchased by consumers (bottled Diet Coke®) state, and continue to state, that Diet Coke® contains aspartame, but do not disclose saccharin, and do not disclose that the fountain product is actually different, let alone that it contains reputedly harmful saccharin.

32. A major part of Coca-Cola's marketing strategy, and a cornerstone to its success, is repeatedly telling consumers that all Coca-Cola products are of a consistent quality (bottled, canned, or fountain) throughout the world. Coca-Cola wants consumers to believe and rely on the representation (however false) that everywhere they see the "Diet Coke®" name and logo, they are always getting the same product.

33. **Other Products.** The extent of confusion as to other products cannot be readily determined. Petitioners are presently seeking to determine whether the Diet Coke situation (i.e., a labeled product differing materially in ingredients from the label-exempt product) exists substantially in other products. In fact, just the process of analyzing the market for such products is difficult, since present regulations do not require but should require a labeled product to disclose that it may contain different ingredients than in an unlabeled formulation.

34. Manufacturers' Awareness of Consumer Confusion. Manufacturers are aware of consumers' confusion (actually, consumers' ignorance of the fact that the nonlabeled product contains different ingredients than the labeled version) and actively seek to prevent this information from reaching consumers, in order to avoid losing sales to competitors. Simply put, manufacturers

such as Coca-Cola deliberately perpetuate and exploit this consumer confusion.

35. Extensive market research has confirmed that consumers are in a state of confusion, because they mistakenly generally believe that the Diet Coca-Cola bottled version and the Diet Coca-Cola fountain version contain identical ingredients.

36. Thus, consumers who read the bottled version of the product all see an ingredient label which lists only aspartame as the sweetener.

37. When consumers purchase the fountain version of the product, they receive an unlabeled container (i.e., which does not list the nutritional contents).

38. Consumer research shows that consumers presume the product is identical.

39. There is generally a difference in taste between the two, which consumers understandably but erroneously ascribe to an inherent difference in the delivery systems, believing that the delivery system imparts a different and inferior taste.

40. In fact, Coca-Cola knows of this confusion, and also knows that a substantial portion of consumers would stop drinking Diet Coke, either in fountain version or altogether, if they knew that it contained saccharin.

41. Further, the difference in taste of the two products is primarily attributable to a different sweetener. However, Coca-Cola continues to use saccharin in Diet Coke in part because it is substantially cheaper for it to produce the product in that form. Indeed, Coca-Cola actually saves approximately $20 million annually by using the cheaper saccharin sweetener in its unlabelled product.

42. Saccharin also has a longer shelf life but consumers generally prefer the taste of dist soft drinks sweetened exclusively with aspartame.

43. Thus, for example, Coca-Cola reaps a compound profit by using saccharin as the primary sweetener for fountain Diet Coke® since: (1) saccharin is substantially cheaper than aspartame and (2) if the product was sweetened with 100% aspartame, it would have a shorter shelf life, thereby causing Coke to incur additional "quality control"-related expenses.

44. Thus, ignoring even the lost revenue from full disclosure, Coca-Cola profits from the lower cost of deceptively using the far cheaper and longer lasting saccharin as the sweetener in the unlabeled version.

45. Further, Coca-Cola's own testing confirms that consumers generally believe that it is the fountain dispensing which causes diet soda products to have an inferior taste to the bottle version, while, in fact, it is the undisclosed ingredients that actually cause this effect.

46. Thus, even ignoring consumers' health concerns, they pay a premium for a lesser product, without having a meaningful way to inquire or discover a difference in the product.

D. ENVIRONMENTAL IMPACT

47. Pursuant to 21 CFR 25.24(a)(11) and (b), no environmental assessment is required with respect to this petition.

E. CERTIFICATION

48. The undersigned counsel for Petitioners certify that, to their best knowledge and belief, this Petition includes all necessary information and views upon which the Petition relies, and that it includes whatever representative data and information known to the petitioners which could be unfavorable to the prayers of the Petition.

F. REQUEST FOR RELIEF

WHEREFORE:

Petitioner requests that the Commission take the following actions:

1. Amend the relevant regulations to require disclosure that whenever nonlabeled versions of branded products differ in content from their labeled versions, the labeled version will be required to disclose, a) That the product has different contents when dispensed in other versions, and b) what those differences are.

2. Amend the relevant regulations to require that whenever a particular substance requiring heightened disclosure on product labels exists in a non-labeled version of a product, that either, (a) the labeled product be required to contain a statement indicating that presence of the substance in the non-labeled product and the corresponding heightened disclosure statement or (b) the non-labeled product be sold under a difference name, or include the product requiring heightened disclosure in its name (e.g., "Diet Coke with saccharin").

3. Amend the relevant regulations to require that different products cannot be marketed under the same name where they contain different ingredients, the inclusion or omission of which would be relevant to a consumer's intent to purchase the product, unless the name of hte labeled product is modified to reflect the presence or absence of those ingredients.

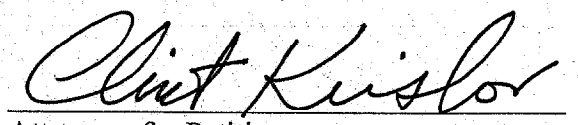
4. Order corrective or remedial advertising be done to eliminate and correct current consumer confusion; and

5. Order such other relief as the Commission deems to be appropriate under the circumstances.

Respectfully submitted,

Judy Zapka

By her attorneys,
Krislov & Associates, Ltd.

By: 
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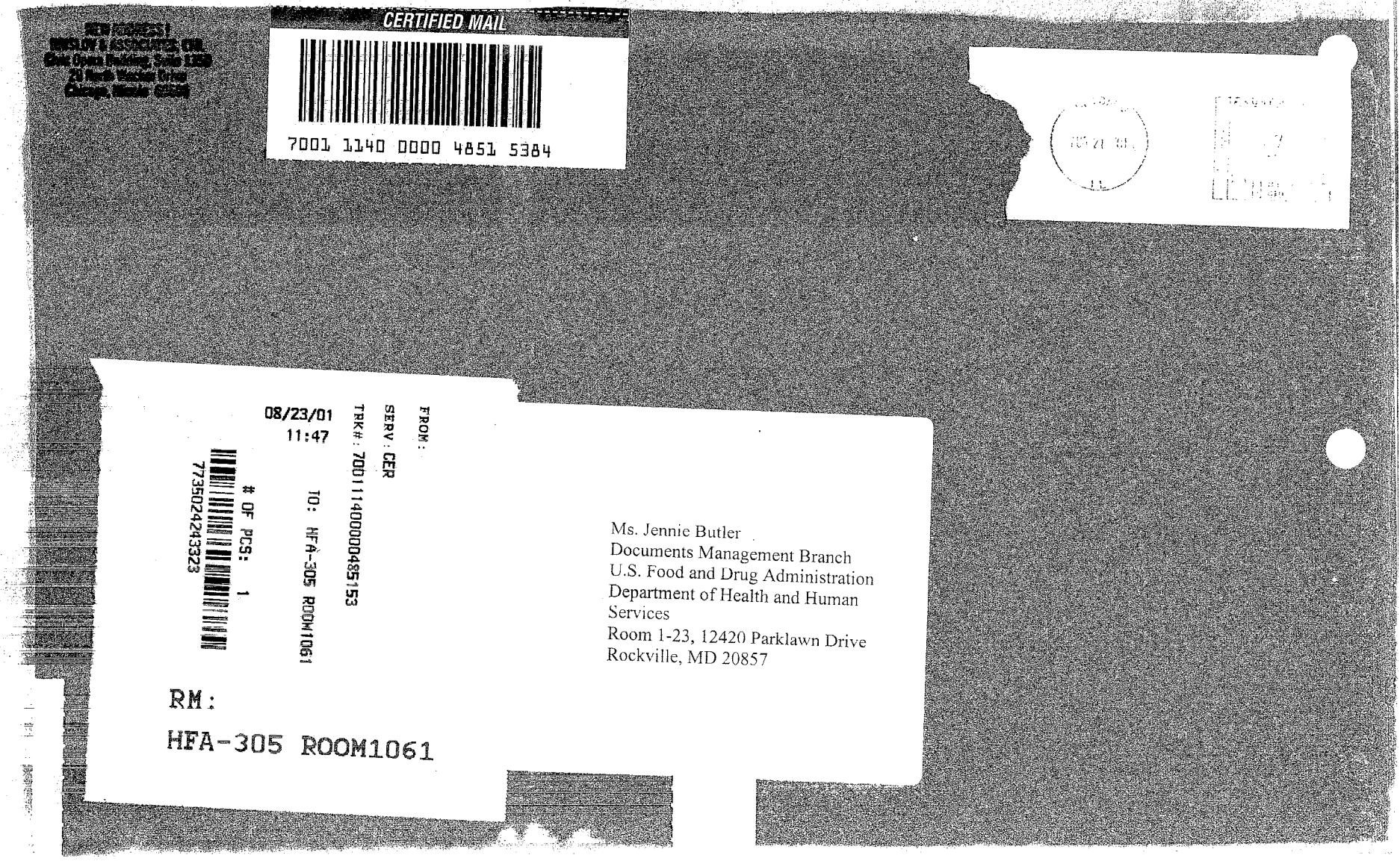
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