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DIRECT DIAL (202) 737-4282

'00 DEC 22 P2:11

December 22, 2000

Docket No. 98N-0337
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Application for Exemption

Dear Sir or Madam:

On behalf of Block Drug Company, Inc. (Block), we are submitting the enclosed letter to Dr. Charles A. Ganley and Amendment to the Application for Exemption for BC® analgesic powder (two doses) originally submitted to the Docket by Block on January 28, 2000, as amended on August 22, 2000. Three copies of each document are enclosed.

If there are any questions, please contact me at (202) 737-4282.

Sincerely,

Robert A. Dormer

RAD/MLB/dad

Enclosures

98N-0337

AMD1

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DIRECT DIAL (202) 737-5600

DEC 22 P2:12

December 22, 2000

Charles J. Ganley, M.D.
Director, Division of Over-the-Counter Drug Products
Office of Drug Evaluation V (HFD-560)
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
9201 Corporate Boulevard, Room S205
Rockville, Maryland 20850

Re: Docket No. 98N-0337: Application for Exemption

Dear Dr. Ganley:

INTRODUCTION

On January 28, 2000, Block Drug Company, Inc. (Block) submitted an Application for Exemption (Application) from certain over-the-counter (OTC) drug product labeling requirements contained in 21 C.F.R. § 201.66 (the Regulation). Block's Application pertains to BC® analgesic powder (two doses).[1] Block amended the Application on August 22, 2000.[2]

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1 While this Application pertains only to Block's BC® analgesic powder (two doses), the issues that prevent Block from complying with the Regulation for this product are present in 21 other SKUs that Block markets. Enclosed with this letter is a supplement to the Application, incorporating minor modifications discussed elsewhere in this letter.

2 Block had originally submitted a version of its Application that redacted information

Block demonstrated that due to the unique configuration of the outer envelope that contains two glassine envelopes that each surround one dose of the product, Block's label cannot comply with this Regulation, as we understand the scope and meaning of the Regulation. As a result of Block's desire to comply with both the spirit and letter of the Regulation, Block presented two options that are feasible from a financial and operational standpoint, which, if accepted by FDA, would be alternative means of complying with the Regulation.

Option 1 would essentially maintain Block's current packaging. The information required by the Regulation would be presented with some modifications to the formatting and type size requirements. Option 2 (the less desired option) would necessitate a modification of the packaging of the product by adding a flap or a fifth panel that would be folded under the shrink-wrap. Under this option, some of the information required to be presented to the consumer under the Regulation would appear on that flap. In addition, under Option 2, all the information required to be provided to a prospective purchaser would be presented to the customer at the point of purchase on a tray placed on store shelves to display the product. Under either option all information required by FDA would clearly be available to the consumer when making a decision as to whether to purchase the product as well as when using the product.[3]

As Block noted in the Application, there has been a long and uninterrupted history of safe use of Block's analgesic powders. Block is unaware of <u>any</u> consumer complaints regarding inability to read the label on Block's analgesic powders. For this reason alone, Block's BC® analgesic powder is an appropriate candidate for an exemption from certain of the labeling requirements. Indeed, if FDA truly intends to provide a meaningful exemption process in which reasonable alternatives are considered and granted for products that are sold in unique package configurations, and that are unable to comply with the letter

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the company had determined was confidential commercial information and/or trade secrets. As a condition to responding to Block's Application, FDA required Block to submit an unredacted copy to the Docket. As a result, Block submitted unredacted copies to the Docket and waived confidentiality for that information.

3 We earlier demonstrated that altering the equipment that manufactures and packages the products at issue would be a difficult, time-consuming, and very expensive process.

of the Regulation, Block's BC® analgesic powder, which has a long history of safe use, would be the best candidate for an exemption.

By letter dated August 28, 2000, FDA responded to the Application (Response). The Response provided helpful insights into FDA's positions on Block's Application. FDA encouraged Block to supplement the Application. In addition, Block now has the benefit of FDA's recent guidance in the area of requesting exemptions from the Regulation.[4] In this letter, we are supplementing our earlier Application by including some information and views that we did not earlier present to FDA, and seeking reconsideration of the denial of Block's Application.

We also will demonstrate below that unless FDA grants the Application, the agency will be jeopardizing rights guaranteed by the United States Constitution and applicable statutes. For instance, we will show that requiring Block to alter its trade dress, including the present package configuration, would be a violation of Block's rights under the Fifth Amendment. In sum, Block again requests that FDA grant the company an exemption from the OTC drug labeling requirements for its BC® analgesic powder.

I. Option 1

A. FDA Cannot Expect Block to Alter Its Principal Display Panel or Increase the Size of the Package

Block's Application noted that the package at issue is an envelope: the front of the package is the Principal Display Panel (PDP), and the back of the package is the only space available for the Drug Facts information mandated by the Regulation. The Response rejected Option 1 by stating that Block could move some of the information required by the Regulation to the PDP. FDA concluded that the total surface area available to bear labeling includes all surfaces of the outside container of the retail package. FDA also stated that the flaps could carry some of the Drug Facts labeling.[5] FDA further stated that if Block is unable to utilize the available labeling space as recommended by FDA, increasing the size

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4 Draft Guidance for Industry-Labeling OTC Human Drug Products-Submitting Requests for Exemptions and Deferrals, Dec. 2000 ("Draft Guidance").

5 Response at 1.

of the package would be a solution.[6] Block will further explain why FDA's suggestions are unworkable.

Block has invested considerable resources in developing, establishing, and maintaining its trademark and trade dress for the BC® package. Block's trade dress for the BC® package includes its "'total image and overall appearance' 'as defined by its overall composition and design, including size, shape, color, texture, and graphics.'"[7] Block has been continuously using the oval BC® trademark logo for 40 years, the current trade dress for 25 years, and the current package size for 70-80 years. The brand name, logos, symbols, patterns of colors, and package size and configuration encompassed by its trademark and trade dress represent the commercial, "public" identity of Block and its products. There are, without doubt, many consumers who know Block's products primarily through its protected trade dress. Block has cognizable, protectable property interests in its products' trade dress, with which it pursues its commercial enterprises. As a result, the current PDP and size of product have clearly become a precious and valuable sales tool that Block should not be required to alter.

Furthermore, we are not aware of <u>any</u> product sold by any company that has voluntarily placed the new Drug Facts information on the PDP. Nor is Block's product capable of containing all such information without Block redesigning the packaging configuration. Moreover, FDA is incorrect in its assertion that Block is required to use the PDP for Drug Facts information in the standardized format based on Block's prior utilization of the PDP for "indication" statements.[8] By voluntarily placing the "indication" statements on the PDP many years ago, Block has not waived its property rights with respect to its trademark and trade dress. The "indication" statements Block currently has on the PDP have been on the PDP for many years. Block chose to place that information on the PDP many years ago in a way that would complement its trade dress. This decision to put the "indication" statements on the PDP in a way that complemented rather than interfered with its trademark and trade dress does not support FDA's position that Block can put other information (including the Drug Facts title, the active ingredients, the uses for the product in a new and less clear format) and other formatting tools (such as barlines and hairlines) on the PDP.

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6 Response at 6.

7 <u>Jeffrey Milstein, Inc. v. Gregor, Lawlor, Roth, Inc.</u>, 58 F.3d 27, 31 (2d Cir. 1995)(citations omitted).

8 <u>See</u> Response at 1.

FDA has recognized and accepted the proposition that a company's need to protect its valuable trade dress can form an adequate basis for an exemption from the Regulation. Indeed, in this very matter, FDA acknowledged that Block may consider the color of the PDP to be trade dress and FDA would consider an exemption from color requirements if Block wishes to retain the product's existing trade dress.[9]

In light of the showing presented above that Block's PDP is its trade dress, FDA should not expect Block to alter its PDP to put any of the Drug Facts information on the PDP, particularly when Block has presented reasonable alternatives. Further, as shown below, if FDA effectively requires Block to either use half of the BC® analgesic powder PDP for Drug Facts information, the UPC symbol, the lot number, and the expiration date, or increase the size of the package by 30% by refusing to grant the Application (in either of the options Block has submitted), such action would constitute an unlawful taking of private property pursuant to the Fifth Amendment to the Constitution.

The Fifth Amendment states that "[n]o person shall be ... deprived of life, liberty, or property, without due process of law; nor shall private property be taken for public use without just compensation."[10] Block's trademark (including its trade dress) for the BC® analgesic powder constitutes property interests warranting Fifth Amendment protection.[11]

The applicable analysis for determining whether Block is entitled to protection under the Fifth Amendment involves balancing three discrete factors: "(1) 'the economic impact of the regulation on the claimant'; (2) 'the extent to which the regulation has interfered with distinct investment-backed expectations'; and (3) 'the character of the governmental action.'"[12]

The economic impact if Block is not granted an exemption from the Regulation is significant. Block stands to lose resources that have been devoted to developing,

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9 See id. at 4.

10 U.S. Const. amend. V.

11 See Cabo Distrib. Co., Inc. v. Brady, 821 F.Supp. 601 (N.D. Cal. 1992).

12 Connolly v. Pension Ben. Guaranty Corp., 475 U.S. 211, 224 (1986) (citation omitted).

establishing, and maintaining its commercial identity if Block is forced to alter its PDP significantly, such that Block's commercial identity and position in the marketplace might be threatened. Indeed, as noted above, if an exemption is not granted, the economic impact on Block will apply to Block's BC® analgesic powder and 21 other powder SKU's that Block markets.

FDA's OTC labeling regulation interferes with Block's reasonable investment-backed expectation that it will continue to be allowed to use its trademark and trade dress, as all commercial entities do in the lawful pursuit of business. As mentioned above, over the past 40 years Block has invested considerable resources in marketing and advertising this product, including but not limited to maintaining the integrity of the PDP, in order to increase the visibility of the BC® trademark and trade dress.

As for the character of the intrusion, the Regulation takes Block's property for public use. If FDA denies Block's Application, FDA will be disregarding Block's property interest in its trademark and trade dress. Block will lose unfettered use of its property rights which otherwise afford a mechanism to identify its products, and compete in the marketplace for the sale of its goods.

B. Other Comments on Option 1

FDA's Response raised other issues with regard to whether Block's Option 1 was acceptable. With respect to the Goody's® Headache Powder example cited in the Response, FDA stated that "although we were not able to get all of the required information within the package space, we did not need much additional space."[13] However, increasing the package size of the products at issue by even a small amount is just as costly and impracticable for Block as doubling the package size (a result that FDA concurred would be undesirable).[14] Moreover, as mentioned above, Block has been using the current package size for 70-80 years. The retail stores that sell Block's products, as well as the customers who buy the products, are accustomed to this package size, and increasing the size of the package would likely be detrimental to Block's ability to successfully market the product. Furthermore, FDA's inability to fit all of the required information on the mock-up

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13 Response at 3. Goody's® Headache Powder is another Block product, and presents similar space and size issues.

14 See id.

occurred in spite of using roughly one third of the PDP and the entire back of the package, leaving no room on the back of the package for the UPC symbol, the tamper-evident statement, the lot number, or expiration date. If Block is required to put the UPC symbol on the front of the package as would be necessary if Block were to follow FDA's recommendations, no retail stores would accept the product.

Nor can Block employ the flaps or other alternative spaces for the Drug Facts, as suggested in the Response.[15] First, text cannot be printed across the back of the package in the manner shown in the Goody's mock-up as if the flaps were not there. Even if Block could insert the text across the flaps rotated 90 degrees from the orientation of the front of the package, Block cannot fit all of the Drug Facts information on the package.[16] Second, for operational reasons, Block cannot decrease the margin space so that text can run closer to the flaps. Third, the size of the flaps themselves cannot be decreased to provide more space on the back of the package for the Drug Facts information. Finally, Block has determined that columns do not help, as even if Block were able to utilize the flaps for Drug Facts information (which Block cannot do), this would not enable Block to fit all of the required information on the current package.[17]

In light of these insurmountable obstacles to adopting the observations FDA presented in its Response, FDA should grant the Exemption requested in Option 1.

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15 See id. at 4.

16 See Tab A (standard format rotated 90 degrees) and Tab B (modified format rotated 90 degrees).

17 See Tab C (standard format with columns); Tab D (modified format with columns); Tab E (standard format with columns rotated 90 degrees); and Tab F (modified format with columns rotated 90 degrees).

II. Option 2

Option 2 is legally permissible under the Food, Drug, and Cosmetic Act (FDC Act) and FDA's regulations, and provides a reasonable alternative for complying with the OTC labeling format and content requirements in the event that FDA rejects Option 1. As we discussed in the Application, Block is willing to place a fifth panel under the shrink-wrap that surrounds the package. We recognize and agree with FDA that this fifth panel will not be read by the customer before purchasing the product. To make available to the consumer all of the required information at the time of purchase, Block is prepared to provide an accompanying product tray that will include all of the required information. This tray will hold the individual envelopes of BC® analgesic powder and will be placed on the retail shelves. FDA's concerns about this alternative, including its perceived lack of authority to grant the Exemption on this ground, and practical concerns about the use of the product tray, are unfounded.

In the Response, FDA indicated it was "willing to consider any further information you may be able to provide, regarding how an approach of this type could meet the requirements of the law and applicable regulations." FDA also invited Block to design a fifth panel where the Drug Facts information would be visible at the point of purchase.[18] Below, we will establish that Option 2 is a viable and legal alternative to the mandates set forth in the Regulation.

A. The FDC Act and FDA Regulations Permit the Fifth Flap/Product Tray Combination

The FDC Act and FDA's implementing regulations allow FDA to grant an exemption from the requirement that all of the Drug Facts information be contained on the outside container or wrapper of the package. In particular, Block's request would comply with both sections 201(k) and 502(c) of the Act.

Section 201(k) of the FDC Act defines the term "label" as a "display of written, printed or graphic matter upon the immediate container of any article."[19] This section

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[18] See id. at 5.

[19] 21 U.S.C. § 321(k) (emphasis added).

further provides that all information required by or under the authority of the FDC Act to appear on a label must also appear on the outside container or wrapper of the retail package, or is easily legible through the outside container or wrapper.[20]

Section 201(m) of the FDC Act defines "labeling" as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article."[21] Thus, the FDC Act clearly distinguishes between a "label" and "labeling," even though all labels are also labeling under the Act. According to these definitions, the BC® analgesic powder envelope would be the product label, and the product tray would be considered labeling for the product.

The FDC Act delineates and limits instances where FDA may require certain information to appear on a product's label, as opposed to its labeling. The only specific information statutorily required to be placed on the label is the name and place of business of the manufacturer, packer, or distributor,[22] the net quantity of contents,[23] the established name of the drug,[24] the active ingredients,[25] and the inactive ingredients.[26] Under Option 2,

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20 See id. 21 C.F.R. § 201.10(i) interprets, among other statutes, 21 U.S.C. § 321(k). This regulation allows information to appear on a leaflet accompanying the package whether or not the outer container lacks the room to hold the required information.

21 21 U.S.C. § 321(m).

22 See 21 U.S.C. § 352(b)(1).

23 See id. at § 352(b)(2).

24 See id. at § 352(e)(1)(A)(i).

25 See id. at § 352(e)(1)(A)(ii).

26 See id. at § 352(e)(1)(A)(iii). Block recognizes that Option 2 does not currently present the inactive ingredients on the outer retail package. Block is therefore amending its Application to request that Block be permitted to change the order of the information presented in the Drug Facts box so that the inactive ingredients will appear on the label immediately following the active ingredients. This would allow the outer label of the product to bear the inactive ingredients. Block's amendment to

Block is willing to put each of these required items on the product's label. Whatever authority FDA does or does not have to require a company to provide the customer with the Drug Facts, the agency cannot require that information to appear on a product's label, as opposed to its labeling, except for those facts that are statutorily required to appear on the label. For that reason, 21 C.F.R. § 201.15, (a regulation cited in the Response), which applies to information that must appear on a product's label, is inapplicable here.

Section 502(c) of the FDC Act states that a drug is misbranded

> [i]f any word, statement, or other information required by or under authority of this Chapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness . . . as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use."[27]

The Response improperly relies on this provision to require Drug Facts to appear on the product's label.[28] As noted above, the FDC Act does not require all the Drug Facts to appear on a product's label. Under Block's proposal, all necessary information will be prominently displayed on the product's labeling.

The FDC Act requires other information, such as adequate directions for use and warnings, to be contained either on the label or otherwise in the product's labeling.[29] Thus,

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the Application reflecting this change as well as the modifications discussed elsewhere is enclosed with this letter.

27 21 U.S.C. § 352(c).

28 See Response at 4.

29 See 21 U.S.C. § 352(f). Block notes that FDA has required that a warning statement ("Keep out of reach of children") for drug products containing salicylates be placed on the "label" of the drug product. 21 C.F.R. § 201.314(a). Without reaching the question of whether the FDC Act permits FDA to require this warning on the label, Block is willing to place this warning statement on the outer label of the product. Therefore, Block is amending the Application to request that Block be permitted to change the order of the information presented in the Drug Facts box so that this warning appears directly after the Reye's syndrome warning.

a drug would not be misbranded under section 502 of the FDC Act if the directions for use and warnings are contained in product labeling, rather than on the label itself, so long as that information is "likely to be read and understood by the ordinary individual under customary conditions of purchase and use."[30] This provision permits the Drug Facts information to be placed on labeling, such as a product tray, which in the matter at issue here would remain with the product until it is purchased by a consumer.

FDA noted that placing labeling information on a product tray does not meet the requirements of 21 U.S.C. §§ 321(k) or 352(c), asserting that the tray is not the retail package.[31] However, the "retail package" language of section 321(k) only applies when information is required to appear on a product's label. As shown above, FDA cannot require the Drug Facts to appear on a product's label (as opposed to its labeling).[32]

B. FDA's Statements Support Block's Position

Conclusive support for Block's position that a fifth panel used in conjunction with a product tray can contain the Drug Facts is contained in a February 4, 2000 letter sent by William K. Hubbard, Senior Associate Commissioner for Policy, Planning, and Legislation, to Bruce Kuhlik, Esq.[33] In that letter, citing 64 Fed. Reg. at 13268 and 13283, FDA stated

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30 See 21 U.S.C. § 352(c).

31 Response at 5.

32 FDA also believes that there is no assurance retailers will retain the tray, and that, in convenience stores, particularly at night, consumers would not see the tray. Finally, FDA expresses the concern that the type sizes for the Drug Facts labeling might not be sufficient for consumers to read the labeling on a product tray. Response at 5. As shown below, these concerns are without merit.

33 Letter from William K. Hubbard, Senior Associate Commissioner for Policy, Planning, and Legislation, to Bruce Kuhlik, Esq., 6 (Feb. 4, 2000). The letter indicates that the goal of the rulemaking proceeding has been to set standards for clear, consistent, easy-to-read drug labeling and to minimize the cognitive load that drug labeling places on lay consumers.

that a company could comply with the Regulation "by integrating commonly used techniques, such as the addition or extension of a fifth panel."[34]

More recently, FDA issued its Draft Guidance document, which discussed how FDA would deal with exemption requests based on insufficient labeling space. This document noted that alternative design techniques can be used such as "extended panels and risers, peel back or fold out labels, and mounting products on cardboard cards or placards." Block submits that Option 2 fits squarely within the confines of the alternative techniques described in the Draft Guidance when, as here, it is impossible for Block to alter its PDP without infringing on Block's trade dress.

Moreover, this Option proposed by Block is consistent with the goals and authority expressed by FDA in the preamble to the Regulation to improve a product's labeling. FDA stated that the regulation "is intended to enable consumers to better read and understand OTC drug product labeling and to apply this information to the safe and effective use of OTC drug products."[35] "This section sets forth the content and format requirements for the labeling of all OTC drug products."[36] In discussing its legal authority for the rule, FDA stated that "regulating the order, appearance, and format of OTC drug product labeling is consistent with FDA's authority to ensure that drug labeling conveys all material information to the consumer (sections 201(n) and 502(a) of the Act) and that labeling communicates this information in a manner that is 'likely to be read and understood by the ordinary individual under customary conditions of purchase and use' (section 502(c) of the Act)."[37] It is noteworthy that FDA consistently chose to use the word "labeling", rather than "label" to describe the goals of the Regulation.

Option 2 is consistent with FDA's goals to provide the consumer with all of the relevant information at the point of purchase so that the consumer can make an informed purchasing decision; and ensure that the consumer has the relevant information at the time of use of the product, so that the product will be used safely and effectively. Option 2

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34 Id. at 16.

35 64 Fed. Reg. at 13,275.

36 Id. at 13,286.

37 Id. at 13,275.

meets both objectives, better than alternatives that FDA found acceptable in the Regulation. The product tray will provide all of the information that FDA has deemed relevant to the consumer at the point of purchase. The fifth flap that will be exposed when the shrink-wrap is removed will enable the consumer to read that same information at the time of use of the product in the format and type size required by the Regulation.

Block's proposed use of both the fifth flap and the product tray would enable the consumer to have the information relevant to purchase and use of the product at times relevant to both of those functions. The Drug Facts information will be prominently and conspicuously displayed and be readable and understandable to ensure that all material facts are provided to consumers.[38]

FDA's concern that the product tray will be discarded by retailers is unfounded.[39] The packages of BC® analgesic powder are sold from the tray. The tray provides a neat and orderly display on the counter. Indeed, the design of the product's envelope helps ensure that the tray will not be discarded. The envelope cannot stand on its own. Particularly when the products are sold on wire racks, the tray must accompany all envelopes being displayed for sale or the products will inevitably fall from the racks

In Block's experience, retailers do not throw these trays out. Throwing away the tray would surely create an unsightly mess and it is highly unlikely any retailer would chose to do so, particularly if Block asks retailers to maintain the products on the tray. Block is prepared to place additional statements on the tray about the importance of the retailer retaining the tray with the products being sold.

FDA's additional concern that transactions at gasmarts and other convenience stores would result in customers being unable to read the product tray is also unfounded.[40] Analgesic products are almost never not sold through the store windows of gasmarts and convenience stores. According to a recent survey Block conducted of ten retailers which collectively account for approximately 1,580 stores, only nine stores even had drive-up/walk-up windows; of these nine stores none sell or have sold analgesic products through the windows.

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38 See 64 Fed. Reg. at 13,269.

39 Response at 5.

40 Id.

Even if a minute number of transactions are conducted through drive-up/walk-up windows, the tray labeling complies in every way with the format and content requirements of the Regulation. It is true that customers purchasing our products from a drive-up gasmart or other convenience store might not be able to read all the Drug Facts on the product tray. However, this will be true even if all the required facts were placed on our existing packaging. Consumers will buy the product in a drive-up gasmart before ever seeing the label. We have no quarrel with FDA's view that the Drug Facts should be accessible to the consumer at point of purchase, as well as during usage of the product. However, when consumers buy products through a drive-up window, they will surely not read the label of any product before purchasing it.

Other FDA statements on packaging techniques FDA will accept as alternatives for small packages also support granting the Exemption. Indeed, those accepted techniques are less likely to meet the goals of the OTC labeling regulation than Option 2.

Support for granting Block an exemption can be found with respect to the requirement that the active ingredients be placed on the label.[41] FDA has, by regulation, permitted a drug packaged in a container too small to accommodate the active ingredient information required by section 502(e)(1)(A)(ii) of the FDC Act to provide such information to consumers in a leaflet accompanying the package, provided that the label bears the proprietary name of the drug, the established name of the drug, an identifying lot number, and the name of the manufacturer, packer, or distributor of the drug.[42] If FDA permits use of a leaflet to provide statutorily required information in order to meet the requirement that a consumer have the information at the time of purchase, FDA can and should grant an exemption from a requirement that FDA promulgated by regulation, particularly where FDA provided an exemption procedure in that same regulation.

Finally, FDA has acknowledged that the information required to be provided under the Regulation will vary depending on the product involved. FDA noted in the preamble to the final regulation that products such as lipsticks or lip balms containing sun screen,

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41 FDA regulations also permit the use of leaflets for the declaration of ingredients for cosmetic labeling for small packages provided that certain requirements are met. See 21 C.F.R. § 701.3(i)-(k).

42 21 C.F.R. § 201.10(i).

require only minimal information for the safe and effective use of the products.[43] The agency noted that such products may typically be packaged in small amounts, have a high therapeutic index, carry extremely low risk in actual consumer use situations, provide a favorable public health benefit, require no specified dosage limitation, and require few specific warnings and no general warnings. Employing this logic, surely FDA can and should be flexible in imposing labeling requirements regarding a relatively low risk product such as BC® analgesic powder.

C. Judicial Precedent Supports the Exemption

Block's position is also supported by judicial interpretation of the FDC Act. The Supreme Court has held that literature shipped separately from drugs but which had a "common destination" as the drug is labeling within the meaning of the FDC Act.[44] In the course of determining whether the labeling of a drug bore adequate directions for use, a court found that a company could comply with this requirement where it shipped both a drug and the literature that bore the required information to a common destination, such as to a distributor.[45]

FDA properly relies on a drug's labeling to determine what representations are being made about the product. Product trays are undeniably "labeling" under the Act. Surely, FDA believes that representations on a product tray can suggest the intended uses of the product sold next to the tray. Conversely, FDA must accept the proposition that a product tray can properly be employed to provide valuable information about the product to the consumer. That is exactly what Block has proposed in Option 2.

D. The Product Tray will be a Valuable Supplemental Source of Information

Block's use of a product tray as labeling in addition to the fifth flap satisfies the requirements of the FDC Act. The product tray that would accompany the drug product on

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43 See 64 Fed. Reg. 13,270.

44 Kordel v. United States, 335 U.S. 345, 347-48 (1948).

45 See United States v. Alberty Food Products, 98 F. Supp. 23, 27 (S.D. Cal. 1951), aff'd, 194 F.2d 463 (9th Cir. 1952).

the retail shelf clearly, and in large print, will display all of the information that an individual would need to make an informed decision about whether to purchase the product. The fifth flap that would be revealed when the shrink-wrap was removed after purchase would enable the individual to have all the Drug Facts information, after purchase, that is required under the Regulation. Block is willing to include a statement on the product tray that the customer should be sure to read all of the warnings and directions for use that would be on the inside of the fifth flap prior to use of the product.[46] As noted earlier, Block is also prepared to give instructions to retailers that they should retain the tray as long as the product is being sold by the retailer. Thus, Block's proposed Option 2 both meets and exceeds the requirements of the FDC Act and its underlying policies and the standard for "labeling" set forth in judicial interpretations of the relevant FDC Act provisions.

Whether or not FDA agrees with this analysis and concludes that the FDC Act does not permit FDA to require all of the Drug Facts to appear on the label, surely FDA has the authority to grant an exemption as sought by Block. Indeed, according to the Consumer Healthcare Products Association (CHPA), FDA stated in a April 17, 2000 meeting with CHPA that paired labeling (i.e., certain information available on the outer container and full labeling available in proximity to the package) might be an acceptable approach for convenience size packages.[47] As Dr. Soller also noted, such configurations have been used for many years on the OTC drug retail shelf.[48]

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46 This statement is not required by any FDA regulation. However, Block is willing to include such a statement in order to convey to the customer the fact that all of the information that is on the product tray will be available when the customer uses the product. See attachment to Block's enclosed amendment to Option 2.

47 See Letter from R. William Soller, Ph.D. to Charles J. Ganley, M.D., Director, Division of OTC Drug Products, CDER, FDA, 1 (October 3, 2000) (hereinafter "Soller Letter").

48 Dr. Soller's letter also demonstrates that 21 C.F.R. § 701.3(i)-(k), which relates to cosmetic ingredient labeling, permits use of a shelf display with leaflets that bear the ingredient labeling as an alternative to placing the information on the outer package. See Soller Letter at 2.

CONCLUSION

FDA provided an exemption process in the Regulation. Surely, FDA intended this exemption procedure to be a meaningful process in which alternatives that comply with the spirit of the Regulation would be granted. FDA simply cannot routinely deny reasonable alternatives that meet the requirements of the FDC Act and the goals of the Regulation. Indeed, if FDA does not grant the exemption sought by Block in January 2000, we cannot foresee any situation where FDA will grant anyone an exemption. FDA should allow Block to implement Option 1 and/or Option 2.

We request that this Application be granted consistent with the expedited time frame set forth in the FDA's December 2000 Draft Guidance document. Although we recognize that the implementation date is still at least eighteen months away, Block will have to explore other options unless the Application is granted. We appreciate FDA's offer to work with Block to develop mutually acceptable labeling in the interim.[49] However, Block needs a permanent solution at the earliest possible time. If we are unable to follow the approaches outlined in this letter, Block will either have to abandon BC® Powder (two doses) and a number of other products or expend considerable financial resources on buying, designing, or retooling equipment to implement the requirements of the Regulation, which will have an adverse impact on consumers.

We trust that you now have sufficient information to grant our request. However, Block believes it is crucial that we meet with appropriate officials in the Center to provide our views and answer any questions you might have. Please do not hesitate to contact me at 202/737-4282 so that we can discuss a time that will be convenient to FDA to have this meeting, and so that we can work closely with FDA to reach a mutually acceptable resolution of this matter.

Sincerely,

Robert A. Dormer

RAD/dad

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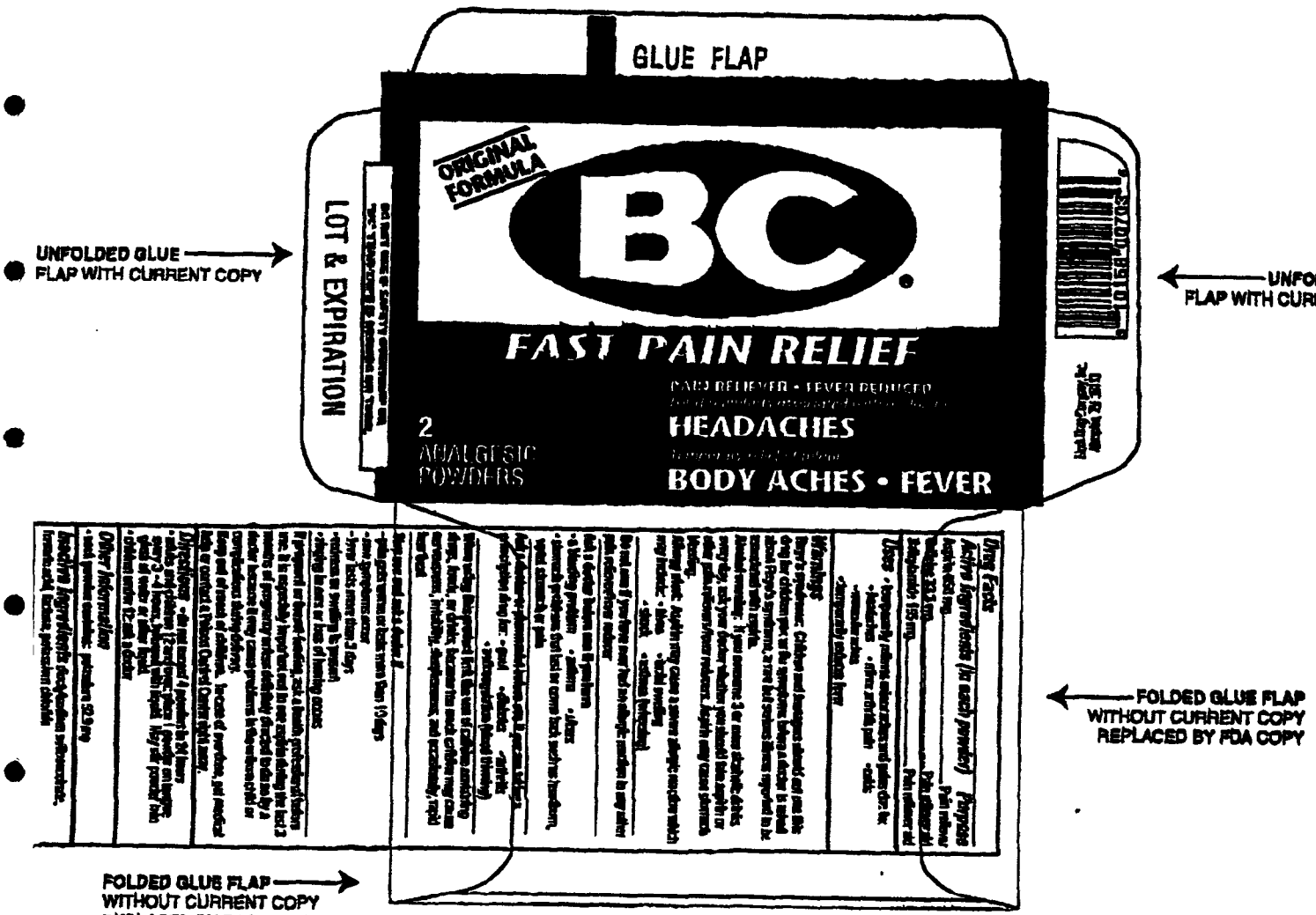
49 See Response at 6.

A



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Project Number: BC-015
File Name: BC 2's-Columns-Stan-Ver Run-on
Revision: 8
Date: 11.02.08
Designer: lam

CREATIVE SERVICES GRAPHICS

B

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Project Number: BC-015
File Name: BC 2's-Columns-Mod-Var Run-on
Revision: 8
Date: 11.02.00
Designer: tsm

CREATIVE SERVICES GRAPHICS

GLUE FLAP

UNFOLDED GLUE FLAP WITH CURRENT COPY

LOT & EXPIRATION

ORIGINAL FORMULA

BC®

FAST PAIN RELIEF

PAIN RELIEVER • FEVER REDUCER

2 ANALGESIC POWDERS

HEADACHES

BODY ACHES • FEVER

UNFOLDED GLUE FLAP WITH CURRENT COPY

FOLDED GLUE FLAP WITHOUT CURRENT COPY REPLACED BY FDA COPY

Drug Facts

Active Ingredients (in each powder) — **Purpose**

Aspirin 850 mg ..... Pain reliever

Caffeine 32.5 mg ..... Pain reliever aid

Salicylamide 325 mg ..... Pain reliever aid

Uses

- temporarily relieves minor aches and pains due to:
  - headache
  - minor arthritis pain
  - colds
  - muscular aches
  - temporarily reduces fever

Warnings

Reye's syndrome: Children and teenagers should not use this drug for chicken pox or flu symptoms before a doctor is asked about Reye's syndrome, a rare but serious illness reported to be associated with aspirin.

Alcohol warning: If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take aspirin or other pain reliever/fever reducers. Aspirin may cause stomach bleeding.

Allergy alert: Aspirin may cause a severe allergic reaction which may include:
- hives
- facial swelling
- shock
- asthma (wheezing)

Drug Facts (continued)

Do not use if you have ever had an allergic reaction to any other pain reliever/fever reducer

Ask a doctor before use if you have:
- a bleeding problem
- hemophilia
- ulcers
- stomach problems that last or come back such as heartburn, upset stomach or pain

Ask a doctor or pharmacist before use if you are taking a prescription drugs:
- diabetes
- anticoagulant (blood thinning)
- arthritis
- gout

When taking this product limit the use of caffeine containing drugs, foods, or drinks, because too much caffeine may cause nervousness, irritability, sleeplessness, and nonshaking, rapid heartbeat.

Stop and ask a doctor if:
- pain gets worse or lasts more than 10 days
- new symptoms occur
- fever lasts more than 3 days
- redness or swelling is present
- ringing in ears or loss of hearing occurs

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use aspirin during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- do not exceed 4 powders in 24 hours
- adults and children 12 and over: place 1 powder on tongue every 2 - 4 hours, followed with drink. Mix the powder into glass of water or other liquid.
- children under 12: ask a doctor

Other Information

- each powder contains: potassium 52.5 mg

Inactive Ingredients dextrodon, sodium citrate, citric acid, lactose, potassium chloride

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Project Number: BC-015
File Name: BC 2's-Columns-Stan-Hor
Revision: 6
Date: 10.10.00
Designer: tom

CREATIVE SERVICES GRAPHICS

UNFOLDED GLUE FLAP WITH CURRENT COPY

UNFOLDED GLU FLAP WITH CURRENT COP

FOLDED GLUE FLAP WITHOUT CURRENT COPY REPLACED BY FDA COPY

FOLDED GLUE FLAP WITHOUT CURRENT COPY REPLACED BY FDA COPY

Drug Facts

Active Ingredients (in each powder) — Purpose

Aspirin 850 mg — Pain reliever

Caffeine 32.5 mg — Pain reliever aid

Salicylamide 195 mg — Pain reliever aid

Uses
- temporarily relieves minor aches and pains due to:
  - headache
  - minor arthritis pain
  - colds
  - muscular aches
- temporarily reduces fever

Warnings

Reye's syndrome: Children and teenagers should not use this drug for children pain or fever symptoms before a doctor is consulted about Reye's syndrome, a rare but serious illness reported to be associated with aspirin.

Alcohol warning: If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take aspirin or other pain reliever/fever reducers. Aspirin may cause stomach bleeding.

Allergy alert: Aspirin may cause a severe allergic reaction which may include: • hives • facial swelling • asthma (wheezing) • shock

Drug Facts (continued)

Do not use if you have ever had an allergic reaction to any other pain reliever/fever reducer

Ask a doctor before use if you have
- a bleeding problem
- asthma
- ulcers
- stomach problems that last or come back such as heartburn, upset stomach or pain

Ask a doctor or pharmacist before use if you are taking a prescription drug for:
- gout
- diabetes
- anticoagulation (blood thinning)
- arthritis

When using this product tell the use of alcohol, sedative drugs, tranq, or blood, because the pain caused may cause nervousness, irritability, sleeplessness, and occasionally, rapid heartbeat

Stop use and ask a doctor if
- pain gets worse or lasts more than 10 days
- new symptoms occur
- redness or swelling is present
- ringing in ears or loss of hearing occurs

If pregnant or in nursing, ask a health professional before use. It is especially important not to use aspirin during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions
- do not exceed 4 powders in 24 hours
- adults and children 12 and over: place 1 powder on tongue every 2 - 4 hours, followed with liquid. May mix powder into glass of water or other liquid.
- children under 12: ask a doctor

Other Information
- each powder contains: potassium 32.5 mg

Inactive Ingredients: dicalcium sulfate, sodium bicarbonate, citric acid, lactose, potassium chloride

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Revision: 0
Date: 10.15.08
Designer: lala

CREATIVE SERVICES GRAPHICS

E

FOLDED GLUE FLAP WITH CURRENT COPY

UNFOLDED GLUE FLAP WITH CURRENT COPY

FOLDED GLUE FLAP WITHOUT CURRENT COPY REPLACED BY FDA COPY

FOLDED GLUE FLAP WITHOUT CURRENT COPY REPLACED BY FDA COPY

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Date: 10.16.00
Designer: tam

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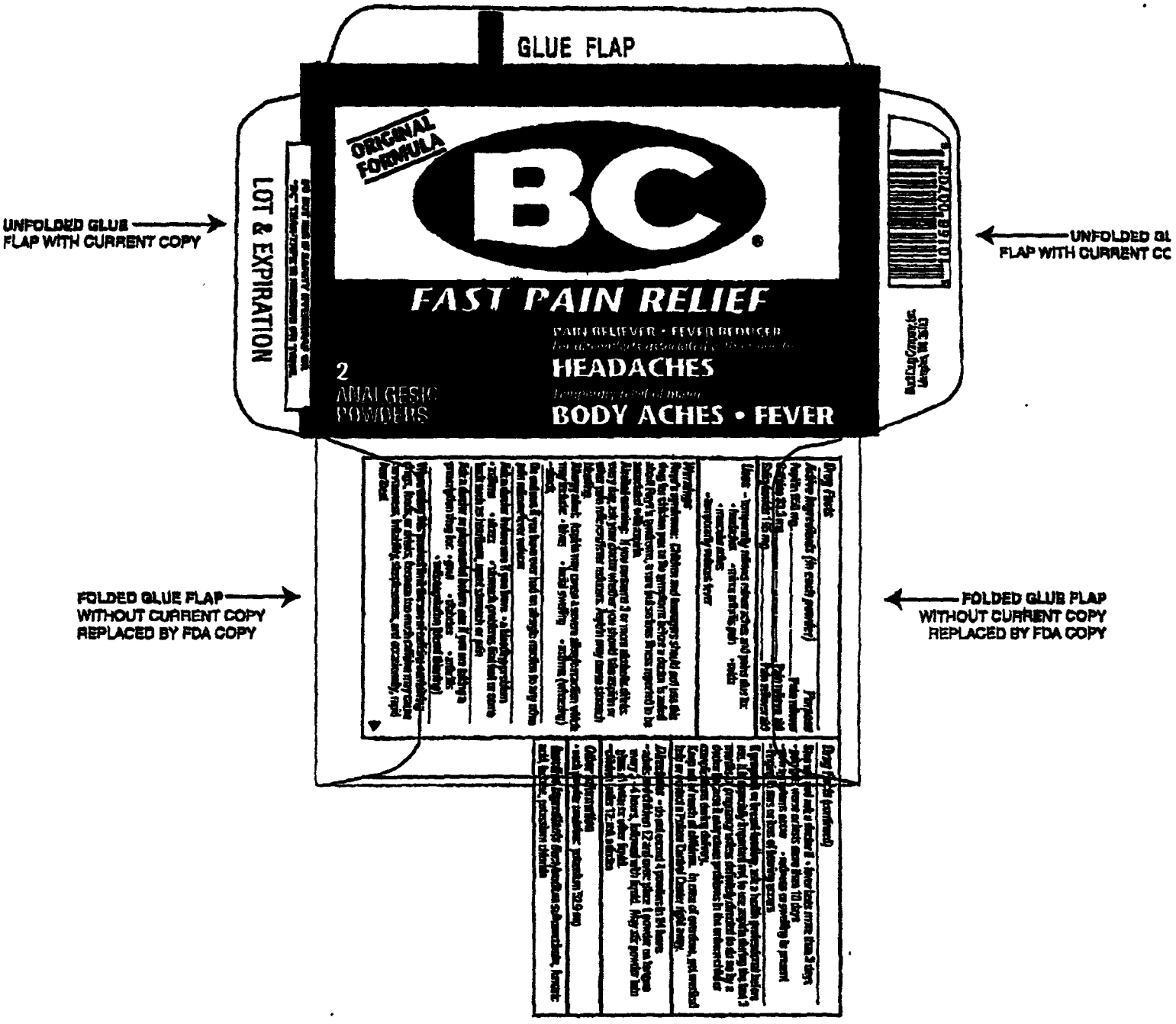

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Revision: 6
Date: 10.16.98
Designer: tam

CREATIVE SERVICES GRAPHICS

Block Drug Company, Inc.
Amendment to Application for Exemption for BC® analgesic powder (two doses)

Block Drug Company, Inc. (Block) is amending Option 2 of its Application for Exemption for BC® analgesic powder (two doses). Block incorporates by reference its January 28, 2000, submission, as amended August 22, 2000, as well as the December 22, 2000, letter from Robert A. Dormer to Dr. Charles A. Ganley.

21 C.F.R. § 201.66(c) Content Requirements

In addition to the previously requested exemption from the requirement in 21 C.F.R. § 201.66(c) that the outside container or wrapper of the retail package contain all of the information specified in paragraphs (c)(1) through (c)(8), Block herein requests exemption from the requirement in 21 C.F.R. § 201.66(c) that the information be placed in the order listed. First, Block requests that it be permitted to place the "inactive ingredients," 21 C.F.R. § 201.66(c)(8), immediately after the "active ingredients," 21 C.F.R. § 201.66(c)(2), on its product label so that the inactive ingredients will be on the outside package at the time of purchase of the product. Second, Block requests that it be permitted to place the "Keep out of reach of children" warning required by 21 C.F.R. § 201.314(a) for products containing salicylates immediately after the Reye's syndrome warning so that this warning will be visible on the outside package at the time of purchase of the product. See Appendix 10.

TABLE OF CONTENTS

Appendix 1 (Current Packaging)

Appendix 2 (Required Information Using Standard Format on Current Package)

Appendix 3 (Required Information Using Modified Format on Current Package)

Appendix 4 (Required Information Using Standard Format Increasing the Package Size)

Appendix 5 (Required Information Using Modified Format Increasing the Package Size)

Appendix 6 (Option 1 Proposed Labeling – Type Size Reduced and Format Revised to Accommodate Information on Package of Same Size as Current Package)

Appendix 7 (Option 1 Annotated Labeling)

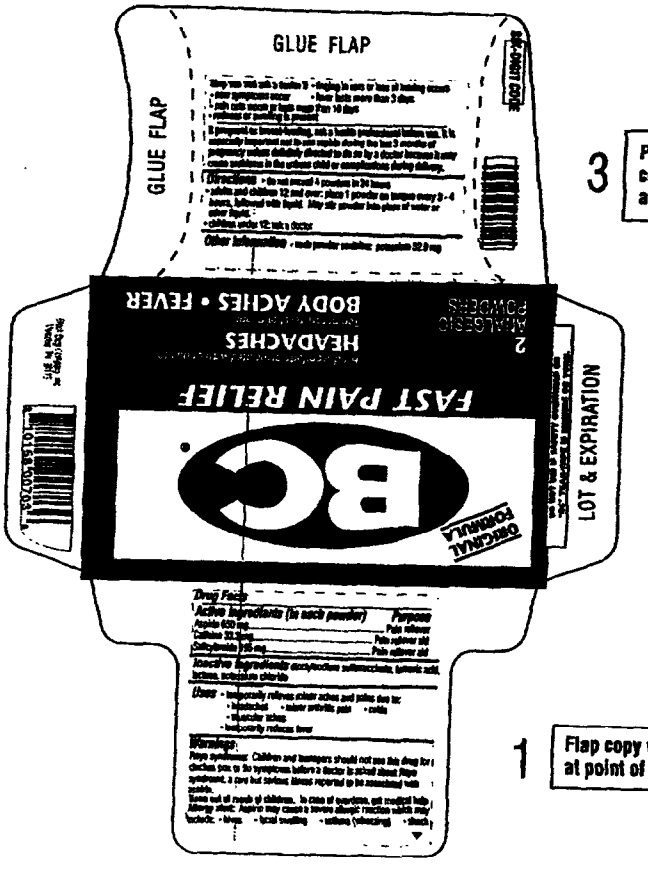
Appendix 8 (Option 2 Proposed Labeling – Package Flap Includes Required Information on Interior and Exterior of Flap)

Appendix 9 (Option 2 Annotated Labeling)

Appendix 10 (Amended Option 2 Annotated Labeling)

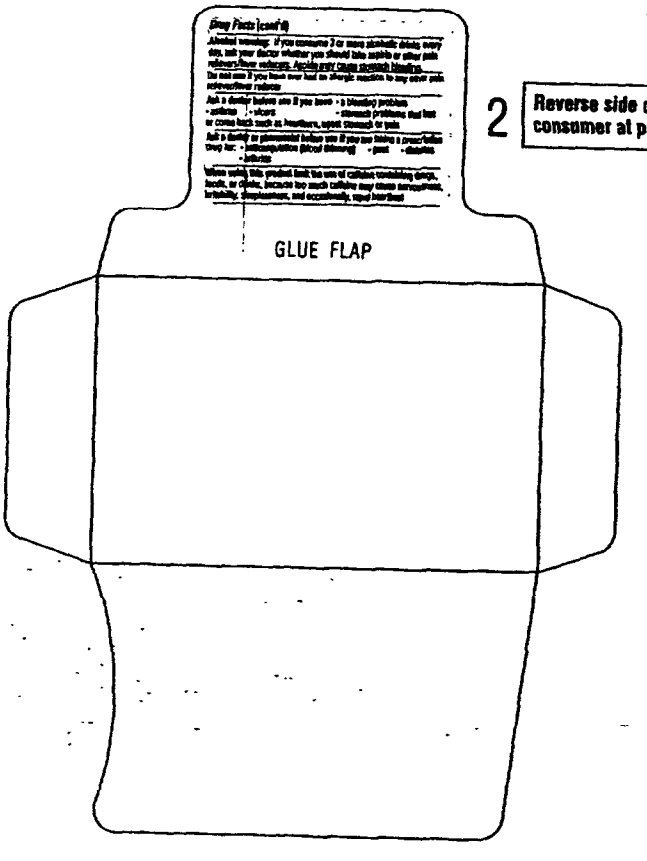
Appendix 10

Amended Option 2 – Annotated Labeling



3 Panel concealed by flap; copy not visible to consumer at point of purchase

1 Flap copy visible to consumer at point of purchase



2 Reverse side of flap; not visible to consumer at point or purchase

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em's between bullets: 2

Project Number: BC-819
File Name: BC 2"x"standard
Revision: 4
Date: 01-04-2000
Designer: tom

NOTE: • GREY DASHED LINE WILL NOT PRINT
• BLUE DASHED LINES REPRESENT THE ENVELOPE OVERLAP
• ALL TOLERANCES MEET REQUIREMENTS

CREATIVE SERVICES GRAPHICS

Memorandum of Telephone Conversation

Date: January 4, 2001

3607 '01 JAN 12

Between: Michelle Butler, Hyman, Phelps & McNamara, P.C., Washington, D.C., (202) 737-7551

and

Gerald M. Rachanow, Regulatory Counsel, Division of OTC Drug Products, FDA

Subject: BC Analgesic Powder (Two Doses)

I called Robert A. Dormer, Esquire, about his December 22, 2000 letter to Dr. Charles Ganley, coded as AMD1 in Docket No. 98N-0337. That letter was in response to the Division of OTC Drug Products' letter of August 28, 2000 concerning an Application for Exemption for BC Analgesic Powder (two doses).

My call was returned by Michelle Butler, Esquire. I informed Ms. Butler that we would like an explanation of a sentence that appears on the second page of Mr. Dormer's letter that states under Option 1 that "The information required by the Regulation would be presented with some modifications to the formatting and type size requirements." I explained that it was not clear to us what these modifications would be and asked that he clarify this statement to identify the modifications so that information would be clear to us while evaluating the petition. I asked that a written explanation be provided (3 copies to the docket and a desk copy to Dr. Ganley). Ms. Butler stated that she would inform Mr. Dormer of our conversation, which concluded amicably.

Gerald M. Rachanow

Gerald M. Rachanow, P.D., J.D.

98N-0337

MT 1

M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: Jan. 10, 2001

FROM: Director
Division of OTC Drug Products, HFD-560

SUBJECT: Material for Docket No. 98N-0337

TO: Dockets Management Branch, HFA-305

[X] The attached material should be placed on public display under the above referenced Docket No.

[X] This material should be cross-referenced to Comment No. AMD1

Charles J. Ganley, M.D.

Attachment