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DIRECT DIAL (202) 737-4282

August 22, 2000

Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

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

Dear Sir or Madam:

As requested by FDA's Division of OTC Drug Products on August 3, 2000, on behalf of Block Drug Company, Inc. (Block), we are amending the exemption request originally submitted to the Docket by Block on January 28, 2000. Because the exemption request contains information that Block considered to be confidential commercial information and/or trade secrets, Block submitted a redacted version to the Docket and a complete, highlighted version to the Division of OTC Drug Products. Block followed the procedures for submitting a request for exemption with confidential information that FDA communicated in its August 9, 1999 Feedback Letter. In that letter, FDA stated that the manufacturer should "make the confidentiality designation in writing at the time the exemption request is initially made."¹ FDA stated that the manufacturer must provide reasons for designation of the information as confidential, preferably in a separate statement since the cover letter of the exemption request will be included in the public docket. Block complied with these procedures, submitting a cover letter with a clear and

¹ Docket No. 98N-0337, Answer 3, Letter from Charles J. Ganley, M.D., Director, Division of OTC Drug Products, CDER, FDA to R. William Soller, Ph.D., Consumer HealthCare Products Association, at 2 (Aug. 9, 1999).

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APP 9

prominent statement that a request for confidentiality was included, as well as a separate statement requesting that certain of the information in the exemption request be designated as confidential.

In spite of the statement in FDA's Feedback Letter that "[t]he agency will make a decision regarding confidentiality shortly after receiving that request,"² Block did not hear from the agency until six months after the exemption request had been submitted. We periodically called FDA on Block's behalf to ascertain the status of the exemption request, but FDA was unable to predict when Block might receive a response to the exemption request. On August 3, 2000, we were contacted by the Division of OTC Drug Products and were told that a decision had been prepared and signed regarding Block's exemption request, but that FDA would not file the redacted version of the exemption request in the Docket. We were told to delete the confidential commercial information and/or trade secrets from the exemption request and resubmit it to the Docket. Only then would FDA send its response to Block's exemption request. Apparently, FDA is currently of the view that confidential information cannot be part of an exemption request notwithstanding the August 1999 letter. According to FDA officials, FDA is no longer following the confidentiality procedures set forth in the August 1999 letter, although to our knowledge this change of policy has never been communicated to industry. Frankly, we are surprised at this change in position given FDA's prior statements in trade association meetings recognizing the need to protect confidential information.

Block disagrees with FDA's recommendation that Block delete the confidential information from the exemption request, as well as FDA's decision not to allow the submission of confidential information in an exemption request. However, Block is threatened with a Hobson's choice: Unless Block either deletes the confidential information from its exemption request or consents to its disclosure, FDA has said it will not rule on Block's exemption request. Consequently, in order to move the process forward and receive FDA's response to the exemption request, Block has decided to waive confidentiality for the information that was the subject of the request for confidentiality. Therefore, Block is amending the exemption request that it originally submitted in January with the following modifications: 1) the statement found on each page that the exemption request "**CONTAINS CONFIDENTIAL COMMERCIAL INFORMATION AND/OR TRADE SECRETS—SECTIONS REDACTED**" has been removed; and 2) the confidential information that was previously redacted has been restored.

² Id.

Accordingly, pursuant to 21 C.F.R. § 201.66(e), Block renews its request for exemption from certain of the OTC labeling requirements in the final rule published on March 17, 1999.³ The subject of this exemption request is BC® analgesic powder (two doses in one package). Block is presenting two approaches for revising its labeling and/or packaging. Block is first requesting exemptions from the format requirements set forth in Option 1. Should FDA deny the exemptions requested in Option 1, Block requests that FDA grant the exemption set forth in Option 2. This application consists of the following information: current labeling for the product; justification for granting the exemptions requested in Option 1, including a complete list of all of the requested exemptions from the labeling requirements; justification for granting the exemption set forth in Option 2, including a complete list of all of the requested exemptions from the labeling requirements; proposed labeling; and annotated labeling. If this exemption request is granted, Block will promptly submit exemption requests for its similarly situated products.

Block is submitting this amended exemption request upon the understanding that FDA will immediately send to us the decision that has been prepared and signed regarding Block's request for exemption from certain of the OTC labeling requirements.

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

Sincerely,



Robert A. Dormer

RAD/MLB/dad

Attachment

³ 64 Fed. Reg. 13254 (Mar. 17, 1999). Please note that the submission of this exemption request does not waive Block's right to challenge the legality of the OTC labeling regulation at a later date. Moreover, Block considers its exemption request to have been filed on January 28, 2000. Given the impending implementation date for the OTC labeling regulation, Block has an urgent need to know FDA's decision with regard to this exemption request.

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I. Introduction

Block Drug Company, Inc. (Block) is the leading manufacturer of over-the-counter (OTC) analgesic powders. Block markets these products under the tradenames BC®, Goody's®, and Stanback®. These headache powders have unique packaging properties. Each dose of powder is packaged in a glassine envelope. In the case of the subject of this application for exemption, BC® analgesic powder (two doses), two of these glassine envelopes are packaged inside an outer envelope that is approximately 3 5/8 inches by 2 3/8 inches. The small size of the envelope allows it to be carried conveniently by customers. The outer envelope is shrink-wrapped to make it tamper-evident, as well as to improve the stability of the products. Due to the configuration of the envelope, the space available for the information required by the OTC regulation is limited to a portion of the back of the envelope. Because the package is an envelope, only two sides may contain printed material. The front of the package is the principal display panel. The back side of the envelope is the only space available for the required labeling, but not all of the back side is available because the flaps that allow the envelope to close must contain the UPC symbol and the tamper-evident statement. Moreover, the engineering of the flaps precludes a flow of labeling information from the back of the package onto the flaps. See Appendix 1 for current packaging. Thus, the labeling for the BC® two dose headache powder cannot comply with either the standard format, see Appendix 2, or the modified format for small packages, see Appendix 3, of the OTC labeling regulation.

The BC®, Goody's®, and Stanback® brands are well-known, highly regarded products that have been sold for many years, primarily in the South. The BC® brand is more than 87 years old. Stanback® and Goody's® have been marketed for 75 and 67 years respectively. These products differ from analgesic tablet, liquid, or capsule remedies because of their powders' portability, ready digestion, and customer loyalty to the small, convenient packaging.

Block's analgesic powders have a long history of safe and effective use. The typical consumer of these products has been using them for many years. These powders, particularly the two dose package at issue here, are typically sold in convenience stores and gasmarts. Block is unaware of any consumer injury or complaints due to inability to read the label or any other evidence that these products present a risk to public health or safety. Powders of this type generally provide a lower-priced alternative for consumers when compared to nationally branded tablet or capsule analgesics. If FDA denies Block's exemption requests, there is a potential that some of these products will no longer be able to be marketed, or that the cost to consumers will increase significantly.

Block has expended considerable time to investigate alternatives for its small packages to comply with the labeling regulation. Block's investigation revealed two options that are feasible from both a financial and an operational standpoint. The first option is to continue using the packaging that Block is currently using and to present all

of the required information in the order set forth in the regulation with some modifications to the formatting and type size requirements that would require exemptions from FDA. This option is Block's first choice. The second option is to modify the packaging for the product by adding a flap or a fifth panel that would be folded under the shrink-wrap and would necessitate an exemption from the provision that all of the required information be printed on the outside container or wrapper of the package. With this option, the consumer will still be able to view all of the labeling information at the point of purchase because Block intends to provide all of the required information in the required format on the tray that is placed on the store shelves to display the product. Block believes that the product labeling under the first option is completely readable by the consumer, and therefore Block requests that FDA consider this second option only in the event that FDA denies Block's exemption request under the first option.

Block's equipment that is used to manufacture and package analgesic powder products is extremely unique. This equipment cannot be purchased directly from a commercial equipment manufacturer. Each piece of equipment is hand-made and literally built from scratch by Block's engineers. Any modification would be a difficult, time consuming, and expensive process.

In the course of investigating a number of alternatives for compliance, Block developed the following information regarding the cost and feasibility of the different alternatives. Continuing to utilize the current packaging and requesting exemptions from certain of the formatting and type size requirements (Option 1) would impose minimal costs on the company and have little impact on operations and therefore have little, if any, cost implications to the consumer. Adding a flap or a fifth panel (Option 2), on the other hand, would result in an average on-going increase of approximately 13% to the cost of goods for the BC® analgesic powder (two doses). This increase results from the cost of modifying equipment plus the annual costs for the change in the packaging component, a decrease in line efficiency, increased scrap, and marginal overhead.

Block also researched five other alternative methods of modifying the packaging (tear pad, outsert label, folded card, skin pack, and riser card), but was forced to reject these alternatives as not feasible due to marketing, trade, and operational issues as well as the prohibitive costs associated with each method.

The tear pad alternative would consist of placing a tear pad with the required information in the standard format on the chip board tray that currently accompanies the product. This alternative would result in an average increase to the cost of goods of approximately 22%. This increase results from the capital cost of purchasing new bar coding equipment and ancillary equipment plus the annual costs for the change in the packaging components, the increase in labor costs because additional people will be needed to manually place the tear pad on the chip board, a decrease in line efficiency, and marginal overhead. In addition to the costs associated with this alternative, the use of a tear pad presents other problems that render it impractical. For example, customers may

choose not to take the tear sheets with them when they purchase the product, or the customers may discard or lose the sheets after leaving the place of purchase. Moreover, retailers, particularly small convenience stores, may choose not to display the tear pads because of a scarcity of shelf space or other reasons. In short, because Block cannot assure that customers will see and read the tear sheets, Block is strongly of the view that the cost of implementing such an alternative is simply not justified.

The outsert label alternative would consist of a folding label attached to the outside of the shrink-wrapped package. This alternative would result in an average increase to the cost of goods of approximately 38%. This increase results from the capital cost of purchasing and installing new equipment plus the annual costs for the change in the packaging components, the increase in labor costs because additional people will be needed to run the equipment, a decrease in line efficiency, increased scrap, and marginal overhead. In addition to these costs, the outsert label presents significant practical problems. Block is concerned that the outsert label may be pulled off of the package at retail which would result in an increased risk of return or destruction of the product. Moreover, Block would also have to ensure that the glue used to attach the outsert label will last for the full expiry period of the product. Finally, if the outsert labels are opened and not folded back up, this will result in a clutter problem on the retailers' shelves which would be unacceptable to them. Again, because of the 38% cost increase that would result from this option, Block does not believe it is acceptable in light of the various practical problems associated with its implementation.

The folded card alternative would consist of the present package glued to the front of a folded card that contains the information in the standard format. This alternative would result in an average increase to the cost of goods of approximately 41%. This increase results from the capital cost of purchasing and installing new equipment plus the annual costs for the change in the packaging components, the increase in labor costs because additional people will be needed to run the equipment, a decrease in line efficiency, increased scrap, and marginal overhead. The folded card option presents additional operational problems, including the fact that the equipment that would be needed to implement this alternative would have to be designed and engineered because it is not commercially available and potential problems with aligning the current package on the folded card. Moreover, the folded card option presents the same trade issues as the outsert label with regard to the ease of removing the labeling information from the package. In fact, the folded cards may result in a clutter problem for retailers that is even worse than the outsert labels because the folded cards are thicker than the outsert labels. Thus, in light of the various practical problems that would result from implementation of this option, Block does not view the 41% cost increase as justified.

The skin pack alternative would consist of the present package shrink-wrapped to a large hang-tag that contains the information in the standard format. This alternative would result in an average increase to the cost of goods of approximately 43%. This increase results from the capital cost of purchasing and installing new equipment plus the

annual costs for the change in the packaging components, the increase in labor costs because additional people will be needed to run the equipment, a decrease in line efficiency, an increase in shipping and storage costs due to the increase in the package size, increased scrap, and marginal overhead. In addition to these costs, the skin pack presents trade problems because the larger card and excess packaging would require added retail space for the products and might result in a retailer carrying fewer of Block's SKUs. Thus, because of the 43% cost increase that would result from this option, Block does not view the skin pack option as acceptable in light of the potential problems associated with its implementation.

The riser card alternative would consist of the present package glued to the front of a riser card that contains the information in the standard format. This alternative would result in an average increase to the cost of goods of approximately 45%. This increase results from the capital cost of purchasing and installing new equipment plus the annual costs for the change in the packaging components, the increase in labor costs because additional people will be needed to run the equipment, a decrease in line efficiency, an increase in shipping and storage costs due to the increase in the package size, increased scrap, and marginal overhead. As with the folded card, the equipment would have to be designed and engineered because it is not commercially available, and properly aligning the package on the riser card may be difficult. In addition to these costs, the riser card presents similar trade problems to the problems associated with the skin pack. The riser card will require additional retail space for the products and might result in a retailer carrying fewer of Block's SKUs. Therefore Block believes that the 45% cost increase is not justified in the face of the practical problems that would result from implementing this option.

As demonstrated above, the tear pad, outsert label, folded card, skin pack, and riser card packaging methods are not feasible from an economic, marketing, trade, or operational standpoint. Block's headache powders compete with the products of much larger competitors whose brands do not solely rely on small size packages as Block's analgesic powders do. Finding the least costly method of compliance is critically important to Block. Block believes the two options set forth below accommodate FDA's concerns while allowing Block to remain competitive in this marketplace. Accordingly, FDA should grant Block's exemption requests.¹

¹ Block is aware that the Alcohol warning and the Allergy alert are not in the correct order on the proposed and annotated labeling. Block is not requesting, under either option, an exemption from the requirement in 21 C.F.R. § 201.66(c) that the information be placed in the order listed. Block will put those warnings in the order listed in the regulation on the actual labeling. For purposes of this exemption request, however, the order of the warnings does not make a difference.

II. Option 1

Block requests that BC® analgesic powder (two doses) be exempt from certain of the format requirements. As stated above, due to the small size of the package, Block is unable to accommodate all of the required information on the outside wrapper or container of the package using either the standardized format, see Appendix 2, or the modified format, see Appendix 3.² Block cannot solve this problem by just increasing the package size to make the required information fit because the size of the resulting package would be double that of the current package. See Appendices 4, 5. As FDA can see with just a glance, doubling the envelope size to accommodate all of the required labeling produced an absurd result. The enlarged package would be impractical, unwieldy, and, quite obviously, ridiculous.

In developing the labeling it is proposing in this application, Block incorporated as many of the formatting requirements as was practicable. Block is only requesting exemption from the few formatting requirements that were absolutely impossible to accommodate on its current packaging. Block believes that the resulting proposed labeling is easily readable and is a reasonable option that complies with the spirit of the OTC labeling regulation. See Appendices 6, 7. Block therefore requests exemptions from the following formatting requirements.

21 C.F.R. § 201.66(d)(1) -- Justification of Subheadings

Block requests an exemption from the requirement that all subheadings be left justified. Block requests that it be permitted to place subheadings in 21 C.F.R. § 201.66(c)(5) on the same horizontal line as a previous statement. Without this exemption, Block would be unable to accommodate all of the required information. The use of bolded text for the subheadings provides sufficient contrast that the subheadings and their respective content may easily be read.

21 C.F.R. §§ 201.66(d)(2), (10)(ii) -- Type Size Requirements

Block requests an exemption from all type size requirements. Specifically, Block requests that it be permitted to reduce the type size for the title "Drug Facts" from 7.1 point type to 5.6 point type, that it be permitted to reduce the type size for the headings from 7 point type to 5.5 point type, and that it be permitted to reduce the type size for

² BC® analgesic powder (two doses) meets the definition of a small package and is eligible to use the modified format. Even using the modified format, Block is unable to accommodate the required information in the required format on the label of this product. Where the modified format provides a requirement different from the standard format, Block requests an exemption from the requirement stated in the modified format.

subheadings and text from 6 point type to 4.5 point type. Without this exemption, Block would be unable to accommodate all of the required information. The differential between the type size of the proposed headings and the type size of the text is sufficient to draw attention to the various headings. Moreover, 4.5 point type size is readable and reasonable in light of FDA's decision to permit the use of type sizes smaller than 6 point type on the labels of other products such as dietary supplements, foods, and cosmetics. See 21 C.F.R. § 101.36(i)(2) (4.5 point type size permitted for nutrition labeling on dietary supplements of small and intermediate size packages); *id.* § 101.9(j)(13) (capital letters measuring 1/16 of an inch permitted for nutrition labeling on foods in small packages); *id.* § 701.3(p) (letter height of declaration of ingredients may be as small as 1/32 of an inch for cosmetic packages that have total surface area available to bear labeling of less than 12 square inches).

21 C.F.R. § 201.66(d)(6) -- Placement of Information Relative to Warning(s) Heading

Block requests an exemption from the requirement that the information described in 21 C.F.R. § 201.66(c)(5) not appear on the same line as the "Warning" or "Warnings" heading. Without this exemption, Block would be unable to accommodate all of the required information. The use of bolded text and type size greater than the subheadings and accompanying text for the heading provides sufficient contrast that the information that follows may be easily read.

21 C.F.R. § 201.66(d)(8) – Hairlines

Block requests an exemption from the requirement that a hairline precede each of the subheadings set forth in 21 C.F.R. § 201.66(c)(5). Without this exemption, Block would be unable to accommodate all of the required information. The use of hairlines preceding each heading and bolded text for the subheadings provides sufficient contrast that the information contained in the Warnings section may be easily read.

Appendix 6 is an original version of how the labeling will appear with the exemptions described above. As is evident from an examination of this labeling, the required information is set forth with ample clarity and legibility. Option 1 is an acceptable substitute for labeling which would otherwise be required.

III. Option 2

If FDA denies the exemptions requested in Option 1, Block requests that BC® analgesic powder (two doses) be exempt from the requirement in 21 C.F.R. § 201.66(c) that all of the required information be printed on the outside container or wrapper of the package.

As stated previously, due to the small size of the package, it is impossible for the BC® analgesic powder (two doses) to accommodate all of the required information on the outside wrapper of the package using either the standard format, see Appendix 2, or the modified format, see Appendix 3. Block therefore proposes to modify the current package to add a flap or a fifth panel that would fold out to display the information that cannot fit on the back of the current package. See Appendices 8, 9. Because the entire package is shrink-wrapped to make the product tamper-evident, as well as to improve the stability of the products, the information on the inside of the flap or folded fifth panel would not be visible until the shrink-wrap is removed and the flap or panel is unfolded. However, this information would still be available to the consumer at the point of purchase because Block will provide all of the information in the standard format required by the OTC regulation on the tray that will be placed on the store shelves to display the product.

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

Block requests 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). Without this exemption, Block is unable to comply with the OTC labeling regulation. This option provides a reasonable method for complying with the regulation because the information that a consumer generally needs when making a purchasing decision (the active ingredients and their purposes, the uses for the product, and the mandatory warnings for the product) will be visible on the package at the point of purchase. The rest of the information, such as directions for use and inactive ingredients, would be visible once the shrink-wrap is removed. Moreover, the consumer will still be provided all of the required information in the required format at the point of purchase by the tray display that will accompany the product. Thus, this alternative balances the need FDA perceives for larger type size and other standardized formatting requirements with Block's ability to market a product valued by consumers for its reasonable cost and convenient size.

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Appendix 7 (Option 1 Annotated Labeling)

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Appendix 9 (Option 2 Annotated Labeling)

Appendix 1

Current Packaging

ORIGINAL FORMULA

BC

FAST PAIN RELIEF

For discomforts associated with or due to
HEADACHES
Temporary relief of minor
BODY ACHES • FEVER

2
ANALGESIC
POWDERS

**READ
NEW LABEL
WARNING**

A



Buck Drug Company, Inc.
Memphis, TN 38113

DIRECTIONS: Adults: Place one powder on tongue and follow with liquid, if you prefer, stir powder into glass of water or other liquid. May be used every three to four hours, up to 4 powders each 24 hours. For children under 12, consult a physician.

WARNINGS: Children and teenagers should not use this medicine for chicken pox or flu symptoms before a doctor is consulted about Reye Syndrome, a rare but serious illness reported to be associated with aspirin. Keep this and all medicines out of children's reach. In case of accidental overdose, contact a physician or poison control center immediately.

As with any drug, if you are pregnant or nursing a baby seek the advice of a health professional before using this product.

IT IS ESPECIALLY IMPORTANT NOT TO USE ASPIRIN DURING THE LAST 3 MONTHS OF PREGNANCY UNLESS

SPECIFICALLY DIRECTED TO DO BY A DOCTOR BECAUSE IT MAY CAUSE PROBLEMS IN THE UNBORN CHILD OR COMPLICATIONS DURING DELIVERY.

Alcohol Warning: If you consume 2 or more alcoholic drinks every day, ask your doctor whether you should take aspirin or other pain relievers/fever reducers. Aspirin may cause stomach bleeding.

This product contains aspirin and should not be taken by individuals who are sensitive to aspirin. If pain persists for more than 10 days or redness is present, consult a physician immediately.

ACTIVE INGREDIENTS: Each packet contains 650 mg. Aspirin, 195 mg. Salicylamide, 33.3 mg. Caffeine.

INACTIVE INGREDIENTS: Docusodium Sulfosuccinate, Fumaric Acid, Lactose and Potassium Chloride.

M92998 EXP 05 04

DO NOT USE IF SAFETY OVERCAP OR "SC" TEAR-TAPE IS MISSING OR TORN.

Appendix 2

Required Information Using Standard Format on Current Package

GLUE FLAP

ORIGINAL FORMULA



FAST PAIN RELIEF

For discomforts associated with or due to

HEADACHES

Temporary relief of minor

BODY ACHES • FEVER

2 ANALGESIC POWDERS

LOT & EXPIRATION

DO NOT USE IF SAFETY OVERWRAP OR "BC" TEAR-TABE IS MISSING OR TORN.



Block Drug Company, Inc. Memphis, TN 38113

Drug Facts

Active ingredients (in each powder)	Purpose
Aspirin 650 mg.....	Pain reliever
Caffeine 33.3 mg.....	Pain reliever aid
Salicylamide 195 mg.....	Pain reliever aid

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

Warnings

Reye syndrome: Children and teenagers should not use this drug for chicken pox or flu symptoms before a doctor is asked about Reye 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 relievers/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

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 limit the use of caffeine containing drugs, foods, or drinks, because too much caffeine 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 • 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 3 - 4 hours, followed with liquid. May stir powder into glass of water or other liquid. • children under 12: ask a doctor

Other information • each powder contains: potassium 52.9 mg

Inactive ingredients dicycloisodium sulfosuccinate, fumaric acid, lactose, potassium chloride



SIX-DIGIT CODE

GLUE FLAP

Title: 8.1 pt.
Headings: 8 pt.
Sub-Headings: 6 pt.
Body: 6 pt.
Leading: 6.5 pt.
Font: Helvetica Condensed
Bullets: 5 pt.
em's between bullets: 2

Project Number: BC-015
File Name: BC 2's-standard
Revision: 4
Date: 12-20-99
Designer: tam

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

Black	PMS 199	PMS 300
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CREATIVE SERVICES GRAPHICS

ALL-STATE® LEGAL 800-222-0510 ED11 RECYCLED



Appendix 3

Required Information Using Modified Format on Current Package

GLUE FLAP

ORIGINAL FORMULA



FAST PAIN RELIEF

2 ANALGESIC POWDERS

For discomforts associated with or due to HEADACHES Temporary relief of minor BODY ACHES • FEVER

LOT & EXPIRATION

DO NOT USE IF SAFETY OVERWRAP OR "BC" TEAR-TAPE IS MISSING OR TORN.



Bock Drug Company, Inc. Memphis, TN 38115

Drug Facts

Active ingredients (in each powder)	Purpose
Aspirin 650 mg.....	Pain reliever
Caffeine 33.3 mg.....	Pain reliever aid
Salicylamide 195 mg.....	Pain reliever aid

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

Warnings

Reye syndrome: Children and teenagers should not use this drug for chicken pox or flu symptoms before a doctor is asked about Reye 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 relievers/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

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 • asthma • ulcers • a bleeding problem • 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 limit the use of caffeine containing drugs, foods, or drinks, because too much caffeine 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 • fever lasts more than 3 days • redness or swelling is present • new symptoms occur • 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 3 - 4 hours, followed with liquid. May stir powder into glass of water or other liquid. • children under 12: ask a doctor

Other information • each powder contains: potassium 52.9 mg

Inactive ingredients dicyclo sodium sulfosuccinate, fumaric acid, lactose, potassium chloride



SIX-DIGIT CODE

GLUE FLAP

Title: 7.1 pt. Headings: 7 pt. Sub-Headings: 6 pt. Body: 6 pt. Leading: 6 pt. Font: Helvetica Condensed Bullets: 5 pt. em's between bullets: 2

Project Number: BC*015 File Name: BC 2's*modified Revision: 6 Date: 08-26-99 Designer: tam

CREATIVE SERVICES GRAPHICS

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

Black	PMS 199	PMS 300
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Appendix 4

Required Information Using Standard Format Increasing the Package Size



LOT & EXPIRATION

DO NOT USE IF SAFETY OVERWRAP OR BC TEAR-TAPE IS MISSING OR TORN.

ORIGINAL FORMULA



FAST PAIN RELIEF

2 ANALGESIC POWDERS

For discomforts associated with or due to HEADACHES

Temporary relief of minor BODY ACHES • FEVER



Block Drug Company, Inc
Memphis, TN 38113

Drug Facts

Active ingredients (in each powder)

Active ingredients (in each powder)	Purpose
Aspirin 650 mg	Pain reliever
Caffeine 33.3 mg	Pain reliever aid
Salicylamide 195 mg	Pain reliever aid

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

Warnings

Reye syndrome: Children and teenagers should not use this drug for chicken pox or flu symptoms before a doctor is asked about Reye 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 relievers/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

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 limit the use of caffeine containing drugs, foods, or drinks, because too much caffeine 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 • fever lasts more than 3 days
• ringing in ears or loss of hearing occurs • redness or swelling is present
• new symptoms occur

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 3 - 4 hours, followed with liquid. May stir powder into glass of water or other liquid.
• children under 12: ask a doctor

Other information • each powder contains: potassium 62.9 mg

Inactive ingredients dicyclo sodium sulfosuccinate, fumaric acid, lactose, potassium chloride

Title: 8.1 pt.
Headings: 8 pt.
Sub-Headings: 6 pt.
Body: 6 pt.
Leading: 6.5 pt.
Font: Helvetica Condensed
Bullets: 5 pt.
em's between bullets: 2

Project Number: BC-015
File Name: BC 2's x-large/standard
Revision: 2
Date: 12-23-99
Designer: tam

NOTE: DASHED LINE WILL NOT PRINT

Black	PMS	PMS
	199	300

CREATIVE SERVICES GRAPHICS

Appendix 5

Required Information Using Modified Format Increasing the Package Size



LOT & EXPIRATION

DO NOT USE IF SAFETY OVERCAP OR BC TEAR-TAPE IS MISSING OR TORN

ORIGINAL FORMULA



FAST PAIN RELIEF

2 ANALGESIC POWDERS

For discomforts associated with or due to
HEADACHES
Temporary relief of minor
BODY ACHES • FEVER



Block Drug Company, Inc
Memphis, TN 38113

Drug Facts

Active Ingredients (in each powder)	Purpose
Aspirin 650 mg	Pain reliever
Caffeine 33.3 mg	Pain reliever aid
Salicylamide 195 mg	Pain reliever aid

Uses • temporarily relieves minor aches and pains due to:
• headaches • minor arthritis pain • colic • muscular aches
• temporarily reduces fever

Warnings
Reye syndrome: Children and teenagers should not use this drug for chicken pox or flu symptoms before a doctor is asked about Reye 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 relievers/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
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 limit the use of caffeine containing drugs, foods, or drinks, because too much caffeine 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 • fever lasts more than 3 days • ringing in ears or loss of hearing occurs • redness or swelling is present • new symptoms occur
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 3 - 4 hours, followed with liquid. May stir powder into glass of water or other liquid. • children under 12: ask a doctor

Other information • each powder contains: potassium 52.9 mg

Inactive ingredients dioctylsodium sulfosuccinate, fumaric acid, lactose, potassium chloride

Title: 7.1 pt.
Headings: 7 pt.
Sub-Headings: 6 pt.
Body: 6 pt.
Leading: 6 pt.
Font: Helvetica Condensed
Bullets: 5 pt.
em's between bullets: 2

Project Number: BC*015
File Name: BC 2's x-large/modified
Revision: 1
Date: 12-23-99
Designer: tam

NOTE: DASHED LINE WILL NOT PRINT

Block	Pgs:	Pvc:
	199	302

CREATIVE SERVICES GRAPHICS

Appendix 6

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



Title: 5.6 pt.
 Headings: 5.5 pt.
 Sub-Headings: 4.5 pt.
 Body: 4.5 pt.
 Leading: 4.5 pt.
 Font: Helvetica Condensed
 Bullets: 5 pt.
 em's between bullets: 2
 bar lines: .75

Project Number: BC-Q15
 File Name: BC 2's-final
 Revision: 2
 Date: 10-15-99
 Designer: tam

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

Black	PMS 199	PMS 300

CREATIVE SERVICES
 GRAPHICS

Appendix 7

Option 1 – Annotated Labeling

Sub-headings, body copy and leading reduced from 6 pt. to 4.5 pt.

GLUE FLAP

LOT & EXPIRATION

DO NOT USE IF SAFETY OVERWRAP OR "BC" TEAR TAPE IS MISSING OR TORN.

ORIGINAL FORMULA

BC



10158-00703

FAST PAIN RELIEF

For discomforts associated with or due to

2

ANALGESIC POWDERS

HEADACHES

Temporary relief of minor

BODY ACHES • FEVER

Title reduced from 7.1 pt. to 5.6 pt.

All headings reduced from 7 pt. to 5.5 pt.

Drug Facts	
Active Ingredients (in each powder)	Purpose
Aspirin 650 mg	Pain reliever
Caffeine 33.3 mg	Pain reliever aid
Salicylamide 195 mg	Pain reliever aid
Uses • temporarily relieves minor aches and pains due to: • headaches • minor arthritis pain • colds • muscular aches • temporarily reduces fever	
Warnings Reye syndrome: Children and teenagers should not use this drug for chicken pox or flu symptoms before a doctor is asked about Reye 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 relievers/fever reducers. Aspirin may cause stomach bleeding. Allerg alert: Aspirin may cause a severe allergic reaction which may include: • hives • facial swelling • asthma (wheezing) • shock. 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 • asthma • ulcers • a bleeding problem • 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 limit the use of caffeine containing drugs, foods, or drinks, because too much caffeine 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 • fever lasts more than 3 days • redness or swelling is present • new symptoms occur • 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 3-4 hours, followed with liquid. May stir powder into glass of water or other liquid. • children under 12: ask a doctor.	
Other information • each powder contains: potassium 32.9 mg	
Inactive ingredients dicycloanilium sulfosuccinate, fumaric acid, lactose, potassium chloride	

Copy begins on same line as "Warnings" heading

Hairlines not used

Sub-headings do not begin on separate horizontal lines

SIX-DIGIT CODE

GLUE FLAP

Title: 5.6 pt.
 Headings: 5.5 pt.
 Sub-Headings: 4.5 pt.
 Body: 4.5 pt.
 Leading: 4.5 pt.
 Font: Helvetica Condensed
 Bullets: 5 pt.
 em's between bullets: 2
 bar lines: .75

Project Number: BC*015
 File Name: BC 2's*final
 Revision: 3
 Date: 01-04-2000/
 Designer: tam

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

Black	PMS 199	PMS 300

CREATIVE SERVICES

GRAPHICS

Appendix 8

**Option 2 – Proposed Labeling
Package Flap Includes Required Information on Interior and Exterior of Flap**

**ORIGINAL
FORMULA**

BC®

FAST PAIN RELIEF

**2
ANALGESIC
POWDERS**

For discomforts associated with or due to

HEADACHES

Temporary relief of minor

BODY ACHES • FEVER

GLUE FLAP

Drug Facts

Active Ingredients (in each powder)	Purpose
Aspirin 650 mg.....	Pain reliever
Caffeine 33.3 mg.....	Pain reliever aid
Salicylamide 195 mg.....	Pain reliever aid

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

Warnings

Reye syndrome: Children and teenagers should not use this drug for chicken pox or flu symptoms before a doctor is asked about Reye 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 relievers/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

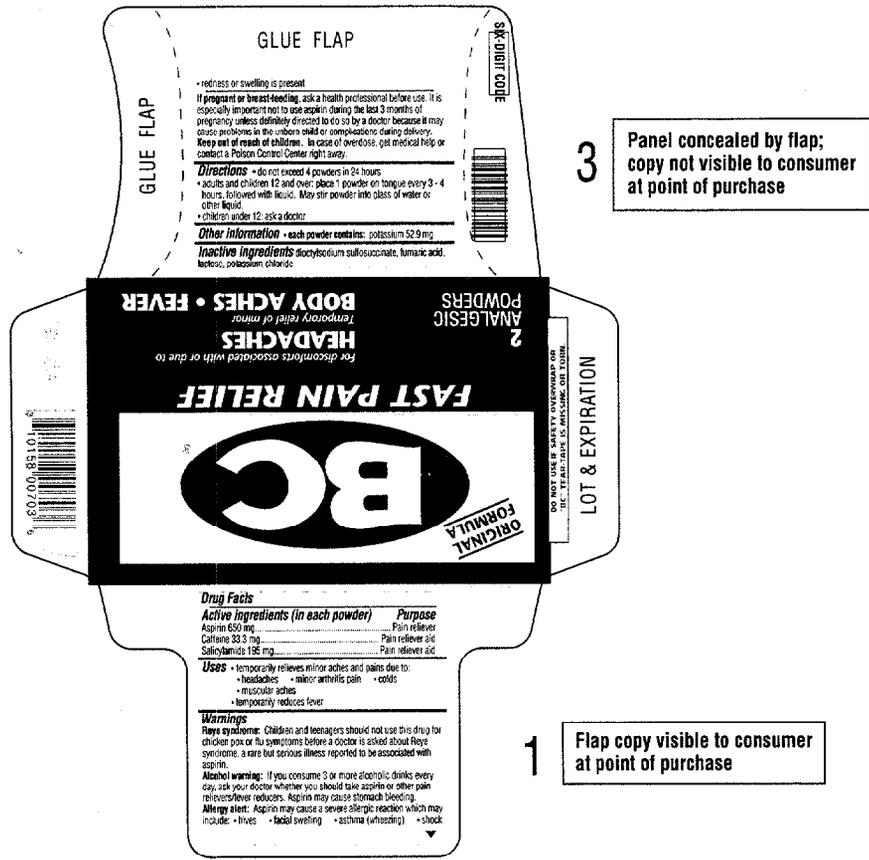
LOT CODE



DO NOT USE IF SAFETY CAP IS MISSING

Appendix 9

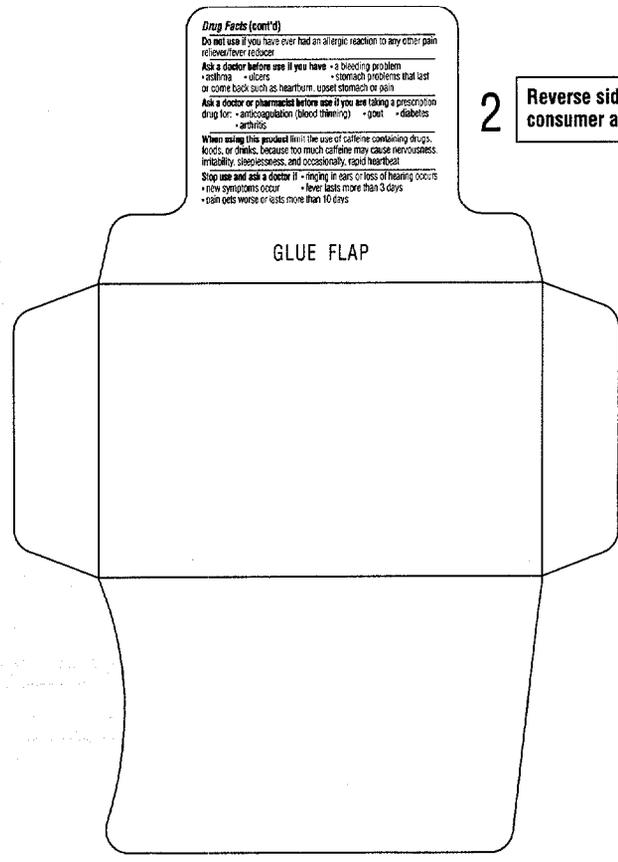
Option 2 – Annotated Labeling



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 of purchase



Title: 8.1 pt.
 Headings: 8 pt.
 Sub-Headings: 6 pt.
 Body: 6 pt.
 Leading: 6.5 pt.
 Font: Helvetica Condensed
 Bullets: 5 pt.
 em's between bullets: 2

Project Number: BC*015
 File Name: BC 2's-standard
 Revision: 4
 Date: 01-04-2000
 Designer: tam

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



PICK UP FROM:

DALLAS
972.831.8200
214.631.3200

DENVER
303.576.9000



WASH DC
202.824.0000
301.657.1300

AUSTIN
512.476.1600

DELIVER TO:

H.P.M. W.D.A.
700 13 ST 1200 5630 FISHER LA 1061
W. DC ROCK MD

SPECIAL INSTRUCTIONS

1.

SENDER SIGNATURE

REFERENCE NO./DESCRIPTION

2. LATRUY TINCOT

RECEIVED BY

FOR OFFICE USE ONLY

MISCELLANEOUS	
LBS	
VIN	
\$	
CHARGES	

ACCOUNT NO.		
012800		
MO.	DAY	YR.

ORDER NUMBER		
TIME DELIVERED		AM PM

CDTM	ZONE	DRIVER
		11
\$		
TOTAL CHARGE		

THE LIABILITY OF ZOOM DELIVERY, INC. AND ITS AFFILIATES IS LIMITED TO THE SUM OF \$1000.00. CLAIMS MUST BE MADE WITHIN 72 HOURS.