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Submitted via www.regulations.gov

May 13, 2024

Dockets Management Staff (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Food and Drug Administration (FDA)[1] Annual Reportable Labeling Changes for New Drug Applications and Abbreviated New Drug Applications for Nonprescription Drug Products; Draft Guidance for Industry; Availability; 89 *Fed. Reg.* 18418-18420 (March 13, 2024); Docket No. FDA–2023–D-5616[2]

Dear Sir or Madam:

The Consumer Healthcare Products Association[3] ("CHPA") submits these comments on the Food and Drug Administration's (FDA's) "Annual Reportable Labeling Changes for New Drug Applications and Abbreviated New Drug Applications for Nonprescription Drug Products; Draft Guidance for Industry" ("Draft Guidance"[4]) issued on March 13, 2024. For more than 143 years, CHPA has served as a vital advocate for the consumer healthcare products industry. A member-based trade association, CHPA represents the leading manufacturers and marketers of OTC medical products. CHPA members provide millions of Americans with safe, effective, and affordable therapies to treat and prevent many common ailments and diseases.

CHPA's proposed changes for the draft guidance text are noted below in blue for inserted text and ~~double strikethrough~~ for deleted text.

[1] The FDA and the Agency are used interchangeably unless otherwise noted.
[2] Food and Drug Administration Annual Reportable Labeling Changes for New Drug Applications and Abbreviated New Drug Applications for Nonprescription Drug Products; Draft Guidance for Industry; Availability; 89 *Fed. Reg.* 18418-18420 (March 13, 2024). Accessed from https://www.govinfo.gov/content/pkg/FR-2024-03-13/pdf/2024-05293.pdf on March 26, 2024.
[3] The Consumer Healthcare Products Association (CHPA), founded in 1881, is the national trade association representing the leading manufacturers and marketers of consumer healthcare products, including over-the-counter (OTC) medicines, dietary supplements, and consumer medical devices. CHPA is committed to empowering self-care by ensuring that Americans have access to products they can count on to be reliable, affordable, and convenient, while also delivering new and better ways to get and stay healthy. Visit www.chpa.org.
[4] Food and Drug Administration Annual Reportable Labeling Changes for New Drug Applications and Abbreviated New Drug Applications for Nonprescription Drug Products; Draft Guidance for Industry. Accessed from https://www.fda.gov/media/176915/download on March 13, 2024.

FDA Draft Guidance Text (Lines 1-3 and 17-21; Footnote 1)

Annual Reportable Labeling Changes for NDAs and ANDAs for Nonprescription Drug Products Guidance for Industry[Draft Guidance Footnote][1]. (Lines 1-3) This guidance has been prepared by the Office of Nonprescription Drugs in the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration. (Footnote 1)

The purpose of this guidance is to provide recommendations to applicants of approved new drug applications (NDAs) and abbreviated new drug applications (ANDAs) for nonprescription drug products on documenting minor labeling changes in the next annual report in accordance with 21 CFR §§ 314.70(d) and 314.97. This guidance also provides examples of such minor labeling changes. (Lines 17-21)

Additional Comments: The Agency notes that the purpose of the draft guidance "…is to provide recommendations to applicants of approved new drug applications (NDAs) and **abbreviated new drug applications (ANDAs)** for nonprescription drug products on documenting minor labeling changes…" (*emphasis added*) Footnote 1 notes that the guidance was prepared by the Office of Nonprescription Drugs (ONPD) in the Center for Drug Evaluation and Research (CDER) at the FDA. However, there is no mention of collaboration or input from the CDER Office of Generic Drugs (OGD) in developing this draft guidance. ONPD should clarify if it consulted with OGD before the initial draft guidance was released for public input. Furthermore, once finalized, this guidance should align with existing OGD practices and procedures to avoid any conflicts for ANDA holders.

FDA Draft Guidance Text (Lines 136-143)

Revising any of the following elements on an instant redeemable or in-pack coupon: expiration date of coupon; information about the package size or sizes of the nonprescription drug product to which the coupon applies, provided that such package size or sizes are consistent with the nonprescription drug product's approved course of treatment count; fixed value discount (e.g., "$1 off"), offer restrictions (e.g., "void if copied, transferred, prohibited, taxed, or restricted"); information required for retailer processing (e.g., UPC or offer code, redemption mailing instructions); and any necessary legal copy (e.g., fraud and policy notice)

CHPA Proposed Text for the FDA Draft Guidance

Revising any of the following elements on an instant redeemable or in-pack coupon: expiration date of coupon; information about the package size or sizes of the nonprescription drug product to which the coupon applies~~, provided that such package size or sizes are consistent with the nonprescription drug product's approved course of treatment count~~; fixed value discount (e.g., "$1 off"), offer restrictions (e.g., "void if copied, transferred, prohibited, taxed, or restricted"); information required for retailer processing (e.g., UPC or offer code, redemption mailing instructions); and any necessary legal copy (e.g., fraud and policy notice)

Additional Comments: The deleted text is inconsistent with current OTC products and how they are commonly sold. Most OTC drug products have more than one course of treatment within the same bottle or SKU[5] which may be used by more than one person in a household (*e.g.*, fever reducers, pain relievers, and cough cold products) or be used for various treatment cycles within the expiration date of the product. Access to a larger count size or pack/SKU size allows multiple users (excepting the case of nasal sprays or other single use products) over multiple treatment courses. More importantly, it provides consumers the ability to relieve their symptoms without having to visit the pharmacy or retail establishment (online or physical store) to obtain additional product each time symptom relief is needed.[6]

FDA Draft Guidance Text (Lines 145-157)

Introducing or adding a new instant redeemable or in-pack coupon (not including peel off PDP coupons) that only includes the nonprescription drug product name, expiration date of coupon, package size of the nonprescription drug product to which the coupon applies, fixed value discount (e.g., $1 off), offer restrictions (e.g., "void if copied, transferred, prohibited, taxed, or restricted"), information required for retailer processing (e.g., UPC or offer code, redemption mailing instructions), and any necessary legal copy (e.g., fraud and policy notice); provided that (1) the coupon is for only the nonprescription drug product it accompanies (i.e., coupon is not for, or does not also address, a different product); (2) if affixed, the coupon does not obscure or change required elements of the labeling; (3) removal of the coupon by the consumer does not affect the readability of required elements of the labeling; and (4) the coupon is not redeemable for a net quantity of the nonprescription drug product that is inconsistent with the nonprescription drug product's approved course of treatment count

CHPA Proposed Text for the FDA Draft Guidance

Introducing or adding a new instant redeemable or in-pack coupon (~~not~~ including peel off PDP coupons that replicate the current PDP) that only includes the nonprescription drug product name, expiration date of coupon, package size of the nonprescription drug product to which the coupon applies, fixed value discount (e.g., $1 off), offer restrictions (e.g., "void if copied, transferred, prohibited, taxed, or restricted"), information required for retailer processing (e.g., UPC or offer code, redemption mailing instructions), and any necessary legal copy (e.g., fraud and policy notice); provided that (1) the instant redeemable coupon is for ~~only~~ any size/SKU of the nonprescription drug product it accompanies ~~(i.e., coupon is not for, or does not also address, a different product)~~; (2) if affixed, the coupon does not obscure or change required elements of the labeling; and (3) removal of the coupon by the consumer does not affect the readability of required elements of the labeling~~, and (4) the coupon is not redeemable for a net quantity of the~~

[5] SKU = stock keeping unit. The SKU is printed on the product label along with the product's universal product code (UPC) and other product information, represents the unique size of the product contents, and is unique to a company.

[6] This suggested change would apply to any place within the FDA draft guidance that references "approved course of treatment count" even for sections not specifically mentioned in CHPA's submission (*e.g.*, Draft Guidance lines 198-203).

~~nonprescription drug product that is inconsistent with the nonprescription drug product's approved course of treatment count~~

Additional Comments: CHPA's position is that in-pack coupons should be allowed as annual reportable changes for not only the same product but also for a different product. The consumer will not see the in-pack coupon, regardless of whether the product on the coupon is the same or different, until after the purchase has been completed. It should be irrelevant whether the product on the in-pack coupon or an instant redeemable coupon is the same or different as the one being purchased. The sponsor would be expected to comply with applicable regulations and submit the required information in its next annual report. Furthermore, if FDA disagrees with this position, the final guidance should explain the Agency's rationale for only allowing in-pack coupons for the same product to be annual reportable.

A peel-off PDP[7] instant redeemable coupon would also be annual reportable if it replicates the entire product PDP found underneath.

Finally, as noted above, the deleted text for criterion #4 is inconsistent with how current OTC products are commonly sold . Most OTC drug products have more than one course of treatment within the same bottle or SKU which may be used by more than one person in a household (*e.g.*, fever reducers, pain relievers, and cough cold products) or be used for various treatment cycles within the expiration date of the product.[6]

FDA Draft Guidance Text (Lines 162-166)
Relocating a logo (or graphic) that appears in the FDA-approved labeling provided that (1) the size of the logo (or graphic) remains the same or decreases; (2) the relocation does not decrease the font size of required elements of labeling; and (3) the relocation does not interfere with (i.e., compete with, interrupt, or distort) or decrease the prominence, readability, or legibility of the required elements of labeling

CHPA Proposed Text for the FDA Draft Guidance
Relocating a logo (or graphic) that appears in the FDA-approved labeling provided that (1) the size of the logo (or graphic) remains the same or decreases; (2) the relocation does not decrease the font size of required elements of labeling; and (3) the relocation does not interfere with (i.e., ~~compete with,~~ interrupt, or distort) or decrease the prominence, readability, or legibility of the required elements of labeling

Additional Comments: "compete with" can be interpreted differently by sponsors and regulators. The remaining qualifiers (*i.e.,* interrupt and distort) are sufficient to guide sponsors about how to generate an updated label that would be appropriate for submission in an annual report.

[7] PDP = Principal Display Panel

FDA Draft Guidance Text (Lines 168-171)
Adjusting the graphic design of the PDP in the FDA-approved labeling after removing a logo (or graphics) or a flag provided that the adjustment does not decrease the font size of required elements of labeling and does not decrease the prominence, readability, or legibility of the required elements of the PDP

CHPA Proposed Text for the FDA Draft Guidance
Adjusting the graphic design of the PDP in the FDA-approved labeling after removing a logo (or graphics) or a flag provided that 21 CFR §§201.61[8], 201.62[9], and 201.66[10] are being followed ~~that the adjustment does not decrease the font size of required elements of labeling and does not decrease the prominence, readability, or legibility of the required elements of the PDP~~

Additional Comments: The deleted text is covered under existing regulations which address font size, prominence, and placement of the required elements of labeling (see 21 CFR §§201.61, 201.62, and 201.66).

FDA Draft Guidance Text (Lines 173-179)
Modifying the orientation of the carton PDP (e.g., vertical to horizontal or vice versa) provided that (1) there are no changes to the carton or container dimensions; (2) there are no changes to the content of the labeling, other than certain minor (e.g., editorial) changes; (3) there is no reduction in font size of the required elements of labeling; (4) the modification does not decrease the prominence, readability, or legibility of the required elements of the PDP; and (5) there are no changes that create insufficient space for the prominent placement of the required elements of labeling

CHPA Proposed Text for the FDA Draft Guidance
Modifying the orientation of the carton PDP (e.g., vertical to horizontal or vice versa) provided that (1) there are no changes to the carton or container dimensions; and (2) there are no changes to the content of the labeling, other than certain minor (e.g., editorial) changes.~~, (3) there is no reduction in font size of the required elements of labeling, (4) the modification does not decrease the prominence, readability, or legibility of the required elements of the PDP, and (5) there are no changes that create insufficient space for the prominent placement of the required elements of labeling.~~ Sponsors would be expected to comply with 21 CFR §§201.61, 201.62, and 201.66.

Additional Comments: Criteria #3, #4, and #5 in the FDA's draft guidance (see lines 176-179 of the FDA Draft Guidance) are covered under existing regulations which address font size, prominence, and placement of the required elements of labeling (see 21 CFR §§201.61, 201.62, and 201.66).

[8] 21 CFR §201.61 Statement of Identify
[9] 21 CFR §201.62 Declaration of net quantity of contents
[10] 21 CFR §201.66 Format and content requirements for over-the-counter (OTC) drug product labeling

FDA Draft Guidance Text (Lines 181-185)
Modifying color schemes on the container label and carton labeling, including minor color changes to the PDP, provided that the modification (1) does not decrease the prominence, readability, or legibility of the required elements of the labeling and (2) does not increase visibility of nonprescription drug product claims while minimizing other required elements of the labeling

CHPA Proposed Text for the FDA Draft Guidance
Modifying color schemes on the container label and carton labeling, including ~~minor~~ color changes to the PDP, provided that the modification (1) does not decrease the prominence, readability, or legibility of the required elements of the labeling and (2) does not increase visibility of nonprescription drug product claims while minimizing other required elements of the labeling

Additional Comments: CHPA is suggesting that the word "minor" be removed as it is unnecessary. Any change in the color scheme would have to meet existing elements as outlined in this section (see FDA draft guidance lines 181-185).

FDA Draft Guidance Text (Lines 190-196)
Adding new package count, excluding multiunit packages, without a change to the drug product's approved container closure system and within its approved stability bracket (i.e., no CMC supplement is required to be submitted for approval), provided that the new package count (1) does not involve a change to labeling content or formatting other than listed net quantity of contents, (2) does not exceed any maximum package count described in the approved application, and (3) is consistent with any approved course of treatment count

CHPA Proposed Text for the FDA Draft Guidance
Adding new package count, excluding multiunit packages, without a change to the drug product's approved container closure system and within its approved stability bracket (i.e., no CMC supplement is required to be submitted for approval), provided that the new package count (1) does not involve a change to labeling content or formatting other than listed net quantity of contents, and (2) does not exceed any maximum package count described in the approved application~~, and (3) is consistent with any approved course of treatment count~~

Additional Comments: CHPA has proposed that criterion #3 be deleted because it is inconsistent with current OTC products and how they are commonly sold. We reiterate that most OTC drug products have more than one course of treatment within the same bottle or SKU which may be used by more than one person in a household (*e.g.*, fever reducers, pain relievers, and cough cold products) or be used for various treatment cycles within the expiration date of the product. Access to a larger count size or pack/SKU size allows multiple users (excepting the case of nasal sprays or other single use products) over multiple treatment courses. More importantly, it provides consumers the ability to relieve their symptoms without having to visit the pharmacy or

retail establishment (online or physical store) to obtain additional product each time symptom relief is needed.

CHPA asks that FDA clarify its definition or interpretation of "maximum package count described in the approved application" when finalizing the guidance.

Furthermore, FDA should provide clarification about how it is defining "multiunit packages." CHPA proposes to define "multiunit packages" as two or more of the same product packaged together (*e.g.*, two or more of the product packaged together either the same pack or tube size or different count size). For example, three 20-count tablet bottles/SKUs or a 20-count tablet + 20-count tablet + 10-count tablet configuration would meet our proposed definition for multipack.

CHPA believes that changes to the number of package units should be permitted as annual reportable changes with no change to labeling or format other than the change to net quantity (even if the DFL[11] is duplicated to enhance its visibility to the consumer).

FDA Draft Guidance Text (Lines 205-208)
Relocating a required tamper-evident statement from inside the DFL to outside the DFL or relocating a required tamper-evident statement approved outside the DFL to another location outside the DFL. The statement must remain prominently placed on the nonprescription drug product package.

Additional Comments: CHPA considers that if the tamper evident statement is within the DFL, it is assumed that it is prominently placed.

Proposed Addition to Section III.A "Examples of Editorial or Similar Minor Labeling Changes" (to be inserted within the FDA Draft Guidance text lines 112-215)

CHPA Proposed Text for the FDA Draft Guidance
Modifying the orientation of the carton (e.g., vertical to horizontal or vice versa) provided that (1) there are no changes to the carton or container dimensions; and (2) there are no changes to the content of the labeling, other than certain minor (e.g., editorial) changes provided that 21 CFR §§201.61, 201.62, and 201.66 are being followed

Additional Comments: CHPA proposes that a new line item be added under Section III.A. to reflect that a change in orientation to the entire product carton can be submitted via annual report. The recommended text is modified language from FDA Draft Guidance lines 173-179 with PDP deleted from line 173 (*i.e.*, "Modifying the orientation of the carton ~~PDP~~ (e.g., vertical to horizontal or vice versa) provided that…"). A sponsor who changed the orientation for the carton would make the corresponding changes to both the PDP and DFL accordingly such that the entire carton was reoriented.

[11] DFL = Drug Facts Label

FDA Draft Guidance Text (Lines 235-242)

When the FDA reviews submitted annual reportable changes, it is FDA's practice to acknowledge the changes at the time of submission of the annual report. Labeling changes submitted in annual reports are not FDA-approved and should not be considered or described as such. FDA would consider the annual reportable changes for approval in any subsequent supplemental NDA or ANDA that the applicant submits. At times, multiple annual reportable changes, especially to the PDP where the outer packaging looks new or different, FDA will request a prior approval supplement be submitted to approve that particular label with multiple changes.

CHPA Proposed Text for the FDA Draft Guidance

When the FDA reviews submitted annual reportable changes, it is FDA's practice to acknowledge the changes at the time of submission of the annual report. Labeling changes submitted in annual reports are not FDA-approved and should not be considered or described as such. FDA would consider the annual reportable changes for approval in any subsequent supplemental NDA or ANDA that the applicant submits. At times, FDA may request a supplement for multiple annual reportable changes~~, especially to the PDP where the outer packaging looks new or different, FDA will request a prior approval supplement be submitted~~ to approve that particular label ~~with multiple changes~~.

> **Additional Comments**: Depending on the types of changes implemented through annual reports, it should be expected that the outer packaging will look new or different to a consumer. For example, a change to the color and orientation of the primary container could be submitted as annual reportable changes and would make the outer packaging look new or different to a consumer. A sponsor would still be expected to comply with all existing regulations and requirements for the said product.

CHPA appreciates the opportunity to provide these recommendations to the Agency. We believe they will improve the effectiveness and efficiency of labeling changes for OTC drug products marketed under an approved application without negatively impacting public health. If you have any questions, I can be reached via the contact information provided below.

Sincerely,

Marcia D. Howard, Ph.D., CAE

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