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Submitted via www.regulations.gov

May 12, 2025

Kelsi Feltz, Office of Information and Regulatory Affairs
U.S. Office of Management and Budget
725 17th Street NW
Washington, DC 20503

Re: Office of Management and Budget Request for Information: Deregulation; 90 *Fed. Reg. 15841-15842* (April 11, 2025); Docket No. OMB-2025-0003[1]

Dear Ms. Feltz:

On April 11, 2025, the U.S. Office of Management and Budget (OMB) issued a request for information for proposals to rescind or replace regulations[2] that stifle American business and ingenuity. OMB specifically asked the public for comments on regulations that are unnecessary, unlawful, unduly burdensome, or unsound.[3] There are a significant number of FDA regulations that either stifle or are burdensome to the consumer healthcare industry. The Consumer Healthcare Products Association (CHPA[4]), founded in 1881, is the national trade association representing the leading manufacturers and marketers of consumer healthcare products, including over-the-counter ("OTC") medicines, OTC medical devices, and dietary supplements. For more than 144 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. It is from this perspective that we offer the following recommendations for consideration to foster innovation in self-care products which ultimately benefits consumers and users of over-the-counter (or nonprescription) drugs, OTC medical devices, and dietary supplements.

[1] Office of Management and Budget Request for Information: Deregulation; 90 *Federal Register* 15481-15482 (April 11, 2025). Accessed from https://www.govinfo.gov/content/pkg/FR-2025-04-11/pdf/2025-06316.pdf on April 16, 2025.
[2] CHPA comments include recommendations for guidances that should be revoked or sunset as they are based on relevant regulations.
[3] See 90 *Federal Register* 15482.
[4] 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.

Issue 1: Unique Device Identification (UDI) Regulation (21 CFR Parts 801 and 830) and Guidance for Industry and FDA Staff: Unique Device Identification (UDI): Policy Regarding Compliance Dates for Class I and Unclassified Devices, Direct Marking, and Global Unique Device Identification Database Requirements for Certain Devices[5] (Regulation, Guidance)

FDA Center: U.S. Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH)

Anticipated impact of revising, removing, or sunsetting the regulation, guidance, or policy: High

Regulated Product Category(ies): Select Class I, Class II, and Unclassified medical devices with OTC marketing status (*i.e.*, medical devices that are typically used by a lay person (consumer) without a prescription from a healthcare provider (HCP)).

Proposed Action: Exempt Unclassified and Class II medical devices that meet the definition of "consumer health product" (see below) from requirement for submissions to the Global UDI Database (GUDID); permit use of the universal product code (UPC) and/or QR code to satisfy the UDI requirement for all devices that meet the definition of consumer health product.

Existing Regulation(s), Guidance(s), or Alternative Approaches that Address Issue Proposed for Deregulation: Guidance for Industry and FDA Staff: Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices, Direct Marking, and Global Unique Device Identification Database Requirements for Certain Devices; 21 CFR § 801.40(d).

Additional Background Information

The UDI (Unique Device Identification) system was created to build a nation-wide active post market surveillance system for medical devices. The system's effectiveness is dependent on the engagement of various stakeholders to generate UDI data input into a database, and the database provides output such as signal detection and predictions. This framework is designed to focus on relying on the UDI to track a medical device through its product lifecycle within the healthcare system, by incorporating various national healthcare databases such as electronic patient records. According to a 2024 report published by the U.S. Government Accountability Office (GAO), a decade after the UDI rule became effective, the progress to leverage UDI to build the active post market surveillance system in

[5] Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices, Direct Marking, and Global Unique Device Identification Database Requirements for Certain Devices; Guidance for Industry and Food and Drug Administration Staff (Final Guidance). Issued July 25, 2022. Accessed from https://www.fda.gov/media/110564/download on April 18, 2025.

healthcare has been very limited due to low stakeholder engagement and high program cost.[6] For OTC medical devices that are used outside of the healthcare system, the effectiveness of the UDI system for these devices is even more diminished.

Most OTC medical devices are purchased in various retail channels and used by the general public outside of healthcare settings. Their uses are not captured in electronic health records (e-HRs), or Centers for Medicare & Medicaid Services (CMS) reimbursement systems. Because the UDI regulation permits use of a UPC code for purposes of meeting the UDI requirement for Class I devices, the UDI information for the majority of OTC medical devices is captured through the UPC code that is scanned at the point of sale in retail establishments. However, this approach relies on retailer engagement and technological capability to scan the UPC code at the retail point of sale. In 2024, the consumer products industry decided to adopt the QR code, in lieu of the UPC code, as the preferred code to be incorporated on packaging labels, which will be scanned at point of sale.[7] The QR code will replace the UPC bar code in the future with a transitioning period starting now. This development will significantly minimize the capturing of UDI information in retail establishments and, once the transition is complete, will essentially render the UPC bar code on OTC medical devices obsolete in the retail environment.

Currently FDA exercises enforcement discretion on the GUDID submission requirements under 21 CFR.300 for Class I devices considered consumer health products.[8] Specifically, the Guidance for Industry and FDA Staff: Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices, Direct Marking, and Global Unique Device Identification Database Requirements for Certain Devices ("Final UDI Guidance") describes FDA's compliance policy regarding GUDID submission requirements for certain Class I devices considered "consumer health products" that are required to bear a UDI on their labels and device packages. The guidance defines "consumer health products" as "510(k)-exempt class I devices that are sold directly to consumers over-the-counter in brick-and-mortar and/or online stores and that do not fall within one or more of the categories [outlined in the guidance]."

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[6] See Government Accountability Office (GAO) Report to Congressional Requesters: Medical Devices – FDA Has Begun Building an Active Postmarket Surveillance System (July 2024). Accessed from https://www.gao.gov/assets/gao-24-106699.pdf on May 11, 2025.

[7] See GS1 White Paper: The retail and consumer goods industries support the transition to QR Codes with GS1 standards. Accessed from https://www.gs1.org/sites/gs1/files/2024-06/global-industry-endorsement-statement-qr-codes-with-gs1-standards.pdf on May 9, 2025.

[8] U.S. FDA Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices, Direct Marking, and Global Unique Device Identification Database Requirements for Certain Devices; Guidance for Industry and Food and Drug Administration Staff (Final Guidance) (July 25, 2025). See page 6. Accessed from https://www.fda.gov/media/110564/download on April 18, 2025.

CHPA proposes that the applicability of the Final UDI Guidance be extended to also cover Unclassified and Class II OTC medical devices that meet the definition of consumer health product under the Final UDI Guidance. It is CHPA's position that requiring manufacturers to enter UDI data for Unclassified and Class II OTC medical devices that are consumer health products in the FDA GUDID database is an unnecessary burden for devices that are intended for sale without a prescription or the assistance of a healthcare professional (HCP). OTC medical device manufacturers execute product retrieval with a combination of GS1 identifiers, product names, bar codes, and lot codes. The UDI is not used in the event a recall is needed for an OTC medical device. In practice, information other than GUDID data is used for product recalls of OTC medical devices, with limited or no negative impact to public safety. The existing tracking systems can also be used for product tracking and collecting safety data.

In addition, CHPA requests that the provision in 21 CFR § 801.40(d) that permits a UPC code to serve as the UDI for Class I devices be extended to Class II and Unclassified devices that meet the definition of consumer health product. Moreover, because the consumer products industry will be transitioning to the QR code, CHPA requests that FDA recognize the QR code as an alternative to the UPC code to satisfy the UDI requirement for all devices that meet the definition of consumer health product.

CHPA requests UDI deregulation for OTC medical devices based on the following criteria:

- Applicability: Class I, Class II, and Unclassified medical devices sold in retail establishments without prescription from healthcare providers that meet the definition of consumer health product under the Final UDI Guidance.
- Expand compliance policy in FDA's Final UDI Guidance regarding GUDID submission requirements for certain Class I devices considered "consumer health products" to also cover Unclassified and Class II devices that meet the definition of consumer health product under the Final UDI Guidance.
- Permit UPC code to serve as UDI for not only Class I devices, but also Class II and Unclassified devices that meet the definition of consumer health product.
- Permit use of QR code in lieu of UPC code to satisfy the UDI requirement for all devices that meet the definition of consumer health product.

Issue 2: Label Negotiation Process for Applications for FDA Approval to Market A New Drug (21 CFR 314)

FDA Center: FDA CDER Office of Nonprescription Drug Products (ONPD)

Anticipated impact of revising, removing, or sunsetting the regulation, guidance, or policy: High

Regulated Product Category(ies): OTC drugs sold under an approved new drug application (NDA) or abbreviated new drug application (ANDA)

Proposed Action: FDA staff should align internally on all requested changes to labeling during each cycle of the negotiation process and convey this information as a single request to the sponsor no less than 14 calendar days before the FDA issues an approval letter.

Existing Regulation(s), Guidance(s), or Alternative Approaches that Address Issue Proposed for Deregulation: None

Additional Background Information
In many instances during the negotiation process for approved labeling for an OTC marketed under an NDA, FDA ONPD staff fail to request updated labels in a single request and instead request changes on a rolling-basis. The lack of a coordinated request (by all FDA staff involved in the review process during the negotiation phase) causes a sponsor to complete multiple production runs for the same label, often with only slight differences between each run. Providing multiple renderings of revised labeling during label negotiations is burdensome (staffing and printing costs) especially when updated labels with these changes are expected in days or possibly even hours.

Issue 3: Use of Representative Labeling During Negotiations for Applications for FDA Approval to Market A New Drug (21 CFR 314) is Not Permitted.

FDA Center: FDA CDER ONPD

Anticipated impact of revising, removing, or sunsetting the regulation, guidance, or policy: High

Regulated Product Category(ies): OTC drugs sold under an NDA or ANDA

Proposed Action: Sponsors should be permitted to use representative labeling for OTC drugs marketed under an approved NDA or ANDA during the negotiation

process. Representative labeling should be used during the review and approval process. Industry will submit all labels as final printed labeling of all shelf keeping units (SKUs) should it be required post-approval.

Existing Regulation(s), Guidance(s), or Alternative Approaches that Address Issue Proposed for Deregulation: None

Additional Background Information

CHPA defines representative labeling (RL) as a pdf rendering of a label or set of labeling that can be used to illustrate the change(s) to existing product labeling or for new labeling. This pdf rendering would serve as the "RL template" and represent either the initial label or proposed changes to the components of the product labeling in the "product family". (A "product family" is all SKUs that have the same National Drug Code (NDC) product code with different package sizes.) The RL will be submitted as draft labeling.

Several years ago, CHPA suggested that FDA pilot a program to identify a procedure to streamline the label change process while minimizing risk to public health. However, no such pilot was ever attempted nor was formal guidance issued or the process changed. CHPA strongly recommends that a sponsor be allowed to use a representative label(s) during the review period and for approval to establish the required edits have been made to all remaining labeling prior to marketing. CHPA proposed that representative labeling could be used in several scenarios including one where the representative label illustrates the label(ing) changes requested by FDA during the review of a pending submission, or a change initiated by FDA, without the need to submit every package size (SKU) within the product family.

The current FDA process for changes to labeling, which covers nearly all changes to labeling no matter how minor, requires that these label changes must be pre-approved. However, there have been rare instances where FDA has allowed a sponsor to use representative labeling. This occasional use of representative labeling demonstrates that FDA can, in fact, use this process, but it also creates uncertainty amongst sponsors. There has been no official communication or guidance from the Agency regarding the use of representative labels. CHPA requests that the current process be replaced with a process that allows manufacturers to submit only one representative label that makes the recommended change during the preapproval and review process. Establishing a formal process for the use of RL would make it available to all sponsors, thereby creating a consistent and level playing field across the regulated industry.

There is a significant burden to the sponsor if their NDA or ANDA has multiple SKUs. If the Agency recommends a last-minute change for the NDA for drug

product A, the sponsor may be required to submit draft labeling for all SKUs. For example, one OTC drug product marketed under an NDA has over 60 labels, all of which would need to be updated under the current process as label changes are being negotiated between the Agency and the sponsor.

The sponsor could certify that the language or label change on its representative label reflects all the changes for all SKUs. The current process of the sponsor being required to submit all draft labels during the review process when there are multiple SKUs involved is overly burdensome and wastes resources (time, staff, and financial).

The Agency would be able to review all labels post-approval. Furthermore, the current requirement of the submission as required under the FDA form 356h is that the sponsor must certify that the data and information in the submission have been reviewed and, to the best of the sponsor's knowledge, are certified to be true and accurate. A willfully false statement is a criminal offense, U.S. Code, title 18, section 1001.

Issue 4: FDA Can Reduce Regulatory Burden for the Agency and Industry by Adhering to Regulation[9] and Its Existing Guidance on "Changes to an Approved NDA or ANDA"[10] for Minor Labeling Changes.

Government Agency: FDA CDER ONPD

Anticipated impact of revising, removing, or sunsetting the regulation, guidance, or policy: High

Regulated Product Category(ies): OTC drugs sold under an NDA or ANDA

Proposed Action: FDA CDER ONPD staff adhere to existing regulation and Agency guidance for minor labeling changes that can be made via a sponsor's annual report according to existing regulations.

Additional Background Information

There is regulatory inconsistency with CDER's process to handle minor label changes for OTC drugs marketed under an NDA, an ANDA, and OTC monographs. Over the course of many years, ONPD has expanded its internal definition of the types of label changes for OTC NDA products considered to be major or moderate changes, requiring a sponsor to submit a prior approval

[9] See 21 CFR 204.66(d)(3).
[10] FDA Guidance for Industry: Changes to an Approved NDA or ANDA (Revision 1, April 2024). Accessed from https://www.fda.gov/media/71846/download on May 2, 2025.

supplement for OTC drugs marketed under an NDA, but not ANDA or OTC monograph. These same types of changes under a ANDA or for OTC monograph drugs do not require prior approval. A prior approval supplement creates unnecessary workload for both FDA and sponsors as many of the commercial-based changes to the label do not present safety concerns. However, they do add significant burden to the Agency and to the sponsor.

CHPA's interpretation of existing regulation[9] and FDA guidance[10] would allow for certain commercial-based label changes to be defined or classified as minor changes to OTC drug labeling. Examples of routine commercial-based label changes include:

- Commercial changes to the label such as new trade dress, a new promotional coupon, a change to or addition of a coupon, or other commercial promotional offers
- Regulatory change to the net contents statement

In the case of changes to graphics, such as colors and logos, FDA's Prior Approval Supplement (PAS) and Changes Being Effected (CBE) reporting requirements hinge on the substantial or moderate "potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug product as these factors may relate to the safety or effectiveness of the drug product" (21 CFR § 314.70(b) and (c)). A change in the colors or logo on the exterior container appears unlikely to affect the identity, strength, quality, purity, or potency of a drug. At most, such changes would typically be "editorial" in nature (*see* 21 CFR § 314.70(d)(2)(x)). However, any such changes should be consistent with applicable requirements, such as the color contrast required for title/headings in the Drug Facts (DF) panel (*see* 21 CFR § 201.66(d)(3)). The Agency could review these changes in the electronic drug listing or the minor changes which the applicant must describe in its next Annual Report (§ 314.70(d)).

The Agency should update its policy to require changes to net quantity as annual reportable changes that are implemented via drug listing when a sponsor is making a change to the net quantity of an OTC drug sold under an approved application. Currently, ONPD requires that all net content changes to an OTC NDA be submitted as prior approval supplements. However, the FDA's guidance for industry notes that minor changes such as "A change in the number of units (e.g., tablets, capsules) or labeled amount (e.g., grams) of nonsterile solid dosage form in a multiple-unit container" are permitted via an annual report.[10] Furthermore, the Agency notes that this type of change is "…considered to have minimal potential to have an adverse effect on the identity, strength, quality, purity, or potency of a drug product as these factors may relate to the safety or effectiveness of the drug product."[10] The practice of

requiring prior approval of changes to the net quantity results in needless delays for consumers to access new products and is inconsistent with established policies for changes to prescription, ANDA, and OTC monograph drug products. The applicant must describe minor changes in its next Annual Report (§ 314.70(d)).

There is a significant delay to industry for NDA regulated OTC drugs when the sponsor is required to submit every label change or a label attachment for prior approval. FDA can significantly reduce its workload and the burden of reviewing draft labeling by adhering to the principles espoused in the cited regulation and guidance that do allow sponsors to make minor changes to the label and report these minor label changes as part of their NDA annual report requirements. In turn, consumers would have faster access to OTC consumer products and innovation without increasing risk to the public's health.

We request that the Agency permit these listed examples as minor changes to the NDA labeling since they have minimal potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug product instead of the current practice of requiring a PAS or CBE for premarket approval.

Issue 5: OTC Drugs Should Be Exempt from Drug Volume Reporting Requirements.

FDA Center: FDA CDER Drug Shortage Staff

Anticipated impact of revising, removing, or sunsetting the regulation, guidance, or policy: High

Regulated Product Category(ies): OTC drugs

Proposed Action: Exempt all OTC drugs from drug volume reporting requirements.

Existing Regulation(s), Existing Guidance(s), or Alternative Approaches that Address Issue Proposed for Deregulation: Reports submitted to FDA online or via email and use of the CDER Direct NextGen Portal.

Additional Background Information

The drug volume reporting (DVR) requirements apply to anyone who registers with the FDA under section 510 of the Federal Food Drug & Cosmetic Act (FD&C Act) for a human or animal drug, including repackers and relabelers. This information is intended to give FDA visibility to the drug supply chain and assist in preventing possible drug shortages such as were

experienced during the Coronavirus pandemic. The FDA should require reporting only for prescription drugs essential to support public health, not for OTC drugs that represent a wide range of therapeutic categories.

The DVR requirement, under the Coronavirus Aid, Relief, and Economic Security (CARES) Act of 2020, imposes a significant administrative burden on pharmaceutical companies by necessitating detailed data collection, verification, and submission. This process consumes substantial human and financial resources, potentially diverting efforts away from critical research and development activities, especially for smaller consumer healthcare companies.

From an industry perspective, DVR has not significantly enhanced FDA's ability to predict or manage drug shortages since it was implemented. For the last several years, pharmaceutical companies have been submitting production volume data, by month and annually, which does not appear to have resulted in actionable steps or insights or prevented drug shortages.

There are several existing tools and systems that address drug shortages. For example, consumers, stakeholder organizations, and healthcare professionals can report potential new shortages by using a publicly available online portal or by emailing FDA. Manufacturers must comply with mandatory reporting requirements for drugs marketed under an approved drug application (which provide essential information about drug shortages). Finally, manufacturers and applicants can utilize the CDER Direct NextGen Portal to report shortages, supply interruptions, recalls, and increased product demand. These are just three examples of options that already exist that should be leveraged to reduce the redundancy of DVR to achieve the desired objectives more efficiently.

Issue 6: FDA Should Sunset the Requirement for Sponsors to Submit Annual Periodic Adverse Drug Experience Reports (PADERs) for the Lifetime of OTC Drug Products Approved under an NDA Three Years After the Initial Quarterly Reports, as Mandated by 21 CFR 314.80. After the First Three Years of Quarterly PADER Submissions, Sponsors Should Submit Annual Reports for the Next Two Years. Following This Five-Year Period, Sponsors Would Be Required to Report Only Serious Adverse Events Which Aligns With the Reporting Requirements for OTC Monograph Drug Products as Outlined in Public Law 109-462.[11]

FDA Center: FDA CDER ONPD

Anticipated impact of revising, removing, or sunsetting the regulation, guidance, or policy: High

Regulated Product Category(ies): OTC drugs sold under an NDA or ANDA

Proposed Action: Initiate rulemaking to modify the length of time by which sponsors are required to submit periodic adverse drug experience reports (PADERs) under 21 CFR 314.80(c)(2)(i). For the first three (3) years after a drug is initially marketed as an OTC medicine, a sponsor would be required to follow the current regulations to submit PADERs quarterly. For years 4-5 post-approval, sponsors will report PADERs annually. For all subsequent years of marketing, OTC drugs sold under an approved NDA would submit serious adverse events using the process used for reporting adverse events that occur for OTC drugs sold under an administrative order (or an OTC monograph).

Existing Text of 21 CFR 314.80(c)(2)(i)[12]

> The applicant must report each adverse drug experience not reported under paragraph (c)(1)(i) of this section at quarterly intervals, for 3 years from the date of approval of the application, and then at annual intervals. The applicant must submit each quarterly report within 30 days of the close of the quarter (the first quarter beginning on the date of approval of the application) and each annual report within 60 days of the anniversary date of approval of the application. Upon written notice, FDA may extend or reestablish the requirement that an applicant submit quarterly reports, or require that the applicant submit reports under this section at different times than those stated. For example, the agency may reestablish a quarterly reporting requirement following the approval of a major supplement.

[11] See Public Law 109-462, the Dietary Supplement and Nonprescription Drug Consumer Protection Act (signed into law by President George Bush on December 22, 2006). Accessed from https://www.congress.gov/109/plaws/publ462/PLAW-109publ462.pdf on May 12, 2025.

[12] 21 CFR 314.80(c)(2)(i) accessed from https://www.ecfr.gov/current/title-21/chapter-I/subchapter-D/part-314/subpart-B/section-314.80 on May 7, 2025.

Followup information to adverse drug experiences submitted in a periodic report may be submitted in the next periodic report.

CHPA Proposed Text for New 21 CFR 314.80(c)(2)(i)(a)

The applicant must report each adverse drug experience not reported under paragraph (c)(1)(i) of this section at quarterly intervals, for 3 years from the date of approval of the application, and then at annual intervals *for 2 additional years for OTC drug products marketed under an approved application, following the initial three year period after approval has been granted by FDA.*[13] The applicant must submit each quarterly report within 30 days of the close of the quarter (the first quarter beginning on the date of approval of the application) and each annual report within 60 days of the anniversary date of approval of the application. Upon written notice, FDA may extend or reestablish the requirement that an applicant submit quarterly reports, or require that the applicant submit reports under this section at different times than those stated. For example, the agency may reestablish a quarterly reporting requirement following the approval of a major supplement. Followup information to adverse drug experiences submitted in a periodic report may be submitted in the next periodic report.

(a) *Five years after initial marketing approval has been granted by FDA for an OTC drug product marketed under an approved application, a sponsor is required to submit serious adverse events in accordance with the requirements for OTC monograph drugs as found in Public Law109-462.*

Existing Regulation(s), Existing Guidance(s), or Alternative Approaches that Address Issue Proposed for Deregulation: 21 CFR 314.80(c)(2)(i) would apply as currently written for sponsors to submit their PADERs quarterly for the first three (3) years after the drug product is approved for sale OTC. After the initial 3 years of market authorization, sponsors would submit PADERs annually for 2 years according to existing regulations. Any serious adverse events that occurred 5-years post-market would be submitted to the Agency via the process currently used for OTC drugs sold under an OTC monograph.[14] Established pharmacovigilance practices would remain in place to identify any potential safety signals for serious adverse events.

Additional Background Information

OTC drug products marketed under an approved application are typically first marketed as a prescription drug for many years. During the entire time of marketing as a prescription drug, the manufacturer is responsible for

[13] Italicized text in blue (*e.g., sample text*) reflects revisions recommended by industry.
[14] See FDA Guidance for Industry: Postmarketing Adverse Event Reporting for Nonprescription Human Drug Products Marketed Without an Approved Application (July 2009). Accessed from https://www.fda.gov/media/77193/download on May 3, 2025.

conducting pharmacovigilance to capture and evaluate adverse event reports for safety signals. Once a drug has been approved for sale OTC, the manufacturer is required to follow established regulations for adverse event reporting whether the drug is sold under an ANDA, NDA, or OTC monograph.

Sponsors have pharmacovigilance systems to capture adverse event reports and identify safety signals across the product's life cycle. A sponsor is required to notify FDA if a safety concern is identified. Additionally, the FDA Adverse Event Reporting System (FAERS) database[15] collects adverse events for drugs marketed in the U.S. not only from manufacturers but also from healthcare professionals and individual patients and consumers, which can be reviewed and evaluated for any potential safety signals. CHPA's proposed changes to the regulation would allow FDA to shift resources to other priorities, and significantly reduce the reporting burden on sponsors while maintaining robust pharmacovigilance procedures throughout the total product lifecycle with little or no negative impact on public safety. FDA would continue to receive annual reports under 21 CFR 314.81(b)(2).

Issue 7: FDA Should Create a Standardized Portal That Allows Manufacturers of FDA-regulated Products from Different Regulatory Categories To Use A Single Website or Platform to Complete Facility and Establishment Registration (21 CFR 207 for drugs, 21 CFR 807 for medical devices, and the Modernization of Cosmetics Regulations Act of 2022 (MoCRA) for cosmetics).

FDA Center: CDER, CDRH, and Human Foods Program (HFP)

Anticipated impact of revising, removing, or sunsetting the regulation, guidance, or policy: Moderate

Regulated Product Category(ies): OTC drugs, OTC cosmetic drugs, and medical devices

Proposed Action: Standardize FDA facility registrations across FDA Centers by creating a single portal that allows manufacturers of products with different regulatory classifications (or categories) to use a single platform to comply with facility and product registration requirements.

Existing Regulation(s), Existing Guidance(s), or Alternative Approaches that Address Issue Proposed for Deregulation: None

[15] FDA Adverse Event Reporting System (FAERS) Database. Accessed from https://www.fda.gov/drugs/drug-approvals-and-databases/fda-adverse-event-reporting-system-faers-database on April 24, 2025.

Additional Background Information
CHPA recommends the Agency streamline the establishment and product registration process for manufacturers of products regulated by different Agency centers. We anticipate that by standardizing the registration process, both FDA and industry could identify operational efficiencies, and reduce the regulatory burdens for manufacturers without any negative consequences to consumers or public health.

Issue 8: OTC Drugs Marketed Under an Approved Application Should Not Be Subject to Pediatric Research Equity Act (PREA) of 2003[16] Requirements.

FDA Center: FDA CDER

Anticipated impact of revising, removing, or sunsetting the regulation, guidance, or policy: Moderate/High

Regulated Product Category(ies): OTC drugs sold under an NDA or ANDA

Proposed Action: FDA should exempt OTC drugs marketed under an approved application from Pediatric Research Equity Act (PREA) requirements.

Existing Regulation(s), Existing Guidance(s), or Alternative Approaches that Address Issue Proposed for Deregulation: The foundation of safety and effectiveness for OTC drugs marketed under an approved drug application are usually based on scientific data included in the marketing authorization for the prescription version of the drug.

Additional Background Information
To satisfy PREA requirements, assessments of safety and effectiveness must be performed in all relevant pediatric age groups unless the assessments are waived or deferred.[17] PREA is redundant because, in most cases, OTC drugs marketed under an approved application were previously marketed as prescription drugs in the relevant age groups for the target population. Pediatric assessments are required for drug products with a new active pharmaceutical ingredient, indication, dosing regimen, or route of administration unless an orphan designation has been granted by the FDA. Requiring pediatric studies under PREA

[16] Public Law 108-155. Pediatric Research Equity Act of 2003. Accessed from https://www.congress.gov/108/plaws/publ155/PLAW-108publ155.pdf on April 25, 2025.
[17] See page 3 of Pediatric Drug Development: Regulatory Considerations - Complying With the Pediatric Research Equity Act and Qualifying for Pediatric Exclusivity Under the Best Pharmaceuticals for Children Act Guidance for Industry (Draft Guidance, Revision 1) (May 2023). Accessed from https://www.fda.gov/media/168201/download on April 25, 2025.

for OTC drugs should not be the default policy or waived only when a sponsor has requested a full or partial waiver.

Issue 9: FDA's Recent Policy Announcement Limiting Individuals Employed at Companies Regulated by FDA, including Pharmaceutical Companies, from Serving as Official Members of FDA Advisory Committees and Panels

FDA Center: FDA CDER, CDRH, and HFP

Anticipated impact of revising, removing, or sunsetting the regulation, guidance, or policy: High

Regulated Product Category(ies): OTC drugs, medical devices, and dietary supplements

Proposed Action: FDA should continue to appoint the non-voting industry liaison representative (ILR) to the various advisory committees and panels as it has for decades.

Existing Regulation(s), Existing Guidance(s), or Alternative Approaches that Address Issue Proposed for Deregulation: None

Additional Background Information

On April 17, 2025, the FDA Commissioner issued a news release that he was announcing a policy directive that limits individuals employed at companies regulated by the FDA, such as pharmaceutical companies, from serving as official members on Agency advisory committees where allowed by statute.[18] CHPA agrees that transparency during the scientific dialogue that occurs during advisory committee meetings is important to establish or maintain trust in the safety and efficacy decisions rendered by the Agency. However, the voice of the regulated industry, either as an individual sponsor or collectively through their trade association, is equally important. The sponsor will have the greatest understanding of the data it has generated during its regulatory and development program.

The current practice is for the Agency to appoint a non-voting ILR, selected by relevant stakeholders, to the advisory committee or panel ("committee"). During official advisory committee meeting proceedings, the ILR may be

[18] FDA News Release: FDA Commissioner Makary Announces New Policy on Individuals Serving on FDA Advisory Committees (April 17, 2025). Accessed from https://www.fda.gov/news-events/press-announcements/fda-commissioner-makary-announces-new-policy-individuals-serving-fda-advisory-committees on April 25, 2025.

recognized by the committee chair to provide clarification of the data, correct misunderstandings or misinterpretations, or pose relevant questions on behalf of the sponsor. Individual sponsors cannot speak during the discussion portion of the meeting unless recognized by the chair, which usually occurs at the request of the ILR. If the industry representative seat is eliminated, the sponsor will have no mechanism to raise clarifying points. For any advisory committee or panel that no longer seats a non-voting ILR, FDA should allow the sponsor or the trade organization to participate on the committee as a non-voting member for that particular meeting during the formal presentations as well as during the discussion period(s), or allow the sponsor to have a closing statement or rebuttal after the discussion ends but prior to any vote.

Issue 10: FDA's Guidance on Format and Content of Over-the-Counter Monograph Order Requests (OMORs) is Overly Burdensome in Its Data Requirements for Well-established OTC Drug Ingredients.

FDA Center: FDA CDER ONPD

Anticipated impact of revising, removing, or sunsetting the regulation, guidance, or policy: High

Regulated Product Category(ies): OTC drugs marketed under an FDA administrative order (*i.e.*, OTC monograph)

Proposed Action: FDA must adopt standards and expectations consistent with historical principles of Generally Recognized as Safe and Effective (GRASE) and the intent of the OTC Monograph User Fee Act (OMUFA), rather than the NDA paradigm, which is overly burdensome.

Existing Regulation(s), Existing Guidance(s), or Alternative Approaches that Address Issue Proposed for Deregulation: Historical principles of GRASE

Additional Background Information

FDA released a draft guidance "Over-the-Counter Monograph Order Requests (OMORs): Format and Content" ("OMORs guidance") on April 13, 2023.[19] Several recommendations provided by FDA in the OMORs guidance are contrary to established GRASE principles for OTC monograph drugs and are more consistent with requirements for a new drug application (NDA). Should FDA finalize the OMORs guidance and impose a de facto requirement for the information detailed in the draft, this would impose a significant burden on

[19] FDA Over-the-Counter Monograph Order Requests: Format and Content (Draft Guidance for Industry) (April 2023). Accessed from https://www.fda.gov/media/167035/download on May 12, 2025.

the OTC industry. Below we reiterate our concerns, centered primarily on data submission principles and types of data FDA should consider when reviewing an OTC Monograph Order Request.

- **Submission of complete data sets for GRASE ingredients should not be required.**

  For ingredients deemed GRASE in an existing final order, complete data summaries (*e.g.*, literature and postmarketing experience summaries) are unnecessary and burdensome. Additionally, for Category 3 ingredients in a former Tentative Final Monograph (TFM) or Category 1 in an Advanced Notice of Proposed Rulemaking (ANPR), a requestor should not be expected to re-submit data supporting GRASE status if the status has already been determined for the ingredient or combination of ingredients.

- **Chemistry, Manufacturing and Controls (CMC) data should not need to be submitted in an OMOR.**

  Chemistry and manufacturing information of drug substances or drug products has not historically been included in OTC monographs and is generally confidential business information owned by the requestor. Under OMUFA, this information is available to FDA on request or during an inspection. It would never be made public.

- **The focus of an OMOR should be on the active ingredient not the drug product.**

  OTC monographs (now orders) do not include information on how to formulate or manufacture finished products and do not include or mandate specific excipients. Manufacturers have the flexibility to use a range of excipients as long as they have supportive safety data. This is codified in 21 CFR 330.1(e).

- **Certification for all evidence related to GRASE status should only be required, *e.g.*, when ingredients have not been recognized as GRASE.**

  A complete summary of all evidence should not be requested when the ingredient is GRASE. Previously submitted data for Cat III (TFM) or Cat I (ANPR) ingredients should not be required.

- **Requests for extensive data in the various modules (*e.g.*, Module 3: Quality Data; and Module 4: Nonclinical Study Reports) should only apply to very specific situations.**

  One example of such a situation is an OMOR requesting a new ingredient GRASE determination for inclusion in a monograph. Pre-submission

meetings with FDA could highlight any new or additional data that may be required to satisfy GRASE in a proposed or final order. Nonclinical summaries should only be requested for ingredients not deemed GRASE in a final order or for OMORs that rely on nonclinical studies as supporting evidence.

- **FDA should not disregard data from published literature due to lack of case level detail; data from older studies should also not be excluded simply because methodology has evolved.**

  Data from the published peer-reviewed literature has always been considered acceptable for the determination of GRASE status. These reports will seldom, if ever, contain the level of detail expected for reports of nonclinical tests and clinical trials submitted in support of NDAs.

In conclusion, CHPA appreciates the opportunity to provide suggestions to OMB that we feel would remove undue regulatory burdens yet minimize risk to the consumer and end-users of OTC medicines, OTC medical devices, and dietary supplements. If implemented, CHPA anticipates ingenuity and innovation will thrive, with the added benefit of potentially reducing the burden to FDA and industry staff and eliminating unnecessary costs, which will ultimately benefit U.S. residents.

Thank you for your time and attention to our recommendations. If you have questions, my contact information is listed below.

Sincerely,

Marcia D. Howard, Ph.D., CAE

Digitally signed by Marcia D. Howard, Ph.D., CAE
Date: 2025.05.12 20:05:19 -04'00'

Marcia D. Howard, Ph.D., CAE
Vice President, Regulatory Affairs & Quality
Email: mhoward@chpa.org
Phone: 202 429 3532

CC: Kelsi Feltz, Office of Information and Regulatory Affairs (via Mailbox: MBX.OMB.DeregIdeas@omb.eop.gov)