NATIONAL HEALTH COUNCIL

July 22, 2026

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

RE: Pharmacy Compounding Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments—Bulk Drug Substances Nominated for Inclusion on the Section 503A Bulk Drug Substances List [FDA-2025-N-6895]

Submitted electronically via regulations.gov

The National Health Council (NHC) appreciates the opportunity to provide comments to the Food and Drug Administration (FDA) in advance of the Pharmacy Compounding Advisory Committee meeting on bulk drug substances nominated for inclusion on the Section 503A Bulk Drug Substances List. The NHC's comments focus on patient-centered principles that should guide FDA's evaluation of nominated bulk drug substances, including the importance of protecting patient safety, preserving appropriate access to compounded medications when they are needed and consistent with legal requirements, ensuring that compounded products are not misunderstood as equivalent to FDA-approved therapies, and supporting transparent, evidence-based oversight.

Created by and for patient organizations more than 100 years ago, the NHC convenes organizations from across the health ecosystem to forge consensus and drive patient-centered health policy. We promote increased access to affordable, high-value, comprehensive, accessible, and sustainable health care. Made up of nearly 200 national health-related organizations and businesses, the NHC's core membership includes the nation's leading patient organizations. Other members include health-related associations and nonprofit organizations including the provider, research, and family caregiver communities; and businesses and organizations representing biopharmaceuticals, devices, diagnostics, generics, and payers.

The NHC recognizes that pharmacy compounding can serve a narrow but important role for patients whose individualized clinical needs cannot be met by an FDA-approved drug product. Patients may require compounded medications because of allergies, inability to tolerate certain excipients, swallowing difficulties, or other patient-specific circumstances that, in a licensed clinician's judgment, warrant compounding. At the same time, compounded products are not FDA-approved, and patients should not be placed at avoidable risk from products that have limited or no clinical data, have not undergone FDA premarket review for safety and effectiveness, or are promoted or used in ways that exceed the evidence available to support them.

The NHC is particularly attentive to this docket because several of the nominated substances are associated with conditions and health needs affecting patient communities represented across the NHC's membership, including ulcerative colitis, inflammatory conditions, obesity, osteoporosis, sleep disorders, and neurologic conditions. For these patients, regulatory decisions about compounded drug substances are not abstract. They may affect whether patients are exposed to products whose safety, effectiveness, quality, dosing, adverse event profile, and role in care are not well understood. They may also determine whether patients and caregivers can distinguish compounded products from FDA-approved therapies or encounter unsupported claims while seeking relief from substantial disease burden. These concerns are especially acute for patients living with chronic, serious, complex, or high-burden conditions, who may be particularly vulnerable to unsupported therapeutic claims, inconsistent product quality, unclear risk communication, or uncertainty about how compounded products differ from FDA-approved drugs.

The NHC encourages FDA and the Pharmacy Compounding Advisory Committee to evaluate nominated bulk drug substances in a manner that recognizes the patient-safety implications of allowing substances that are not components of FDA-approved drugs and may lack an applicable United States Pharmacopeia or National Formulary monograph to be used in compounded products under Section 503A. Under Section 503A, compounded drug products that meet statutory conditions may qualify for exemptions from requirements related to current good manufacturing practice, labeling with adequate directions for use, and FDA approval through a new drug application or abbreviated new drug application. These exemptions are meaningful from the patient perspective because they affect the evidentiary, manufacturing-quality, labeling, and premarket-review expectations that otherwise help ensure patient safety.

The NHC recognizes that, after evaluating the nominated substances based on their physical and chemical characteristics, safety, evidence of effectiveness, and historical use in compounding, FDA has proposed that the substances under consideration not be included on the 503A Bulks List. The NHC supports a cautious, evidence-based approach that gives significant weight to the limitations FDA has identified regarding safety, effectiveness, historical use, and the relevance and quality of the information supporting the nominations. Where the available evidence does not adequately characterize a substance's risks, potential benefits, dosing, quality, or appropriate use, the NHC encourages FDA and the Committee to prioritize patient safety and require those uncertainties to be sufficiently addressed before the substance is considered for inclusion on the 503A Bulks List.

Careful evaluation is particularly important where nominated substances are associated with serious, chronic, or complex conditions, such as ulcerative colitis, obesity, osteoporosis, neurologic conditions, sleep disorders, inflammatory conditions, wound healing, or substance-use-related conditions. Patients in these communities may face substantial unmet need and may be exposed to claims that are not supported by the same evidentiary standards applicable to FDA-approved therapies. Evidence that a substance has been nominated, compounded, marketed, or used for a condition should not be treated as equivalent to evidence that a compounded drug product made with

that substance is safe, effective, appropriately dosed, consistently manufactured, and suitable for use in humans.

The NHC recognizes that the 503A Bulks List evaluation process is not the same as the new drug approval process and that compounding does serve a narrow, legitimate role. However, where the available evidence is limited, indirect, preliminary, nonclinical, poorly controlled, or not specific to the nominated substance, formulation, route of administration, dose, or patient population, FDA should weigh those limitations carefully because patients may otherwise be exposed to products whose risks, benefits, dosing, interactions, contraindications, adverse effects, and long-term consequences are not adequately understood.

The NHC recommends that FDA and the Committee pay particular attention to nominations involving serious chronic conditions that can impose significant symptom burden, treatment complexity, and understandable interest in additional therapeutic options. For example, patients living with ulcerative colitis may experience pain, diarrhea, rectal bleeding, fatigue, weight loss, anemia, urgent or unpredictable symptoms, extraintestinal manifestations, treatment failures, steroid exposure, surgery, and substantial effects on work, education, caregiving, mental health, and daily life. One nominated substance, BPC-157, is associated with use in ulcerative colitis, and FDA has identified potential concerns related to immunogenicity for certain routes of administration, peptide-related impurities, and API characterization. The Committee's discussion and FDA's subsequent decision-making should carefully distinguish between evidence of the substance's use or promotion for ulcerative colitis and evidence that a compounded product made with that substance is safe, effective, appropriately dosed, consistently manufactured, and suitable for use by patients with inflammatory bowel disease.

The NHC also encourages FDA to consider how the intended or promoted uses of nominated bulk drug substances may affect patient understanding and decision-making. When a compounded product is associated with treatment of a chronic disease or another serious or ongoing health need, patients may encounter the product in clinical settings, wellness settings, online marketing, social media, or other channels that do not always distinguish clearly between FDA-approved therapies, investigational products, dietary supplements, compounded drugs, and other interventions. Patients should not be expected to navigate these distinctions without clear, accessible, and accurate information, and the risk of confusion further supports careful evaluation of whether the evidence for a substance is sufficient to justify inclusion on the 503A Bulks List.

The NHC further urges FDA to evaluate safety in a manner that reflects the potential risks associated with compounded products. Safety concerns may arise not only from the intrinsic pharmacology of a substance, but also from how a compounded product is formulated, prepared, and used. Factors of concern include dosing variability, route of administration, impurities, sterility, formulation stability, and interactions with other treatments. Risks may also increase when patients have multiple chronic conditions or complex medication regimens, or when patients may delay, substitute, or discontinue evidence-based care to use a compounded product. These risks are particularly consequential for patients living with chronic, disabling, rare, serious, or complex

conditions, who may already face fragmented care, multiple prescribers, high out-of-pocket costs, complex medication regimens, and uncertainty about treatment options.

FDA's evaluation should also account for the limitations of adverse event detection for compounded products. There are no federal adverse event reporting requirements for 503A compounders, and patients and clinicians may not always recognize or report adverse events associated with compounded medications, particularly when products are obtained from different sources, used outside traditional care pathways, or marketed in ways that do not clearly identify the product as a compounded drug. The NHC encourages FDA to consider whether available adverse event data are sufficient to characterize the safety profile of each nominated bulk drug substance and to be cautious about interpreting an absence of reported adverse events as evidence of safety, particularly where use patterns, exposure levels, product quality, or reporting pathways are not well characterized.

The NHC also recommends that FDA and the Committee consider how a substance's inclusion on the 503A Bulks List impacts patient and provider perceptions. Inclusion on the list may be interpreted by some stakeholders as an endorsement of the safety or effectiveness of a substance for the reviewed uses, even if FDA's decision is narrower and tied to the statutory framework for compounding. FDA should therefore communicate clearly that inclusion on the 503A Bulks List, if granted for any substance, does not mean that FDA has approved compounded drug products containing that substance, determined that the product is safe and effective for a particular disease or condition, or reviewed compounded formulations in the same manner as FDA-approved drugs.

The NHC encourages FDA to make its rationale for each substance's inclusion or exclusion from the 503A Bulks list transparent and understandable to patients, patient organizations, clinicians, compounders, and other stakeholders. FDA's background materials, Committee discussion, and any future documents related to this docket should clearly explain how the Agency considered safety, evidence of effectiveness, physical and chemical characteristics, historical use, and any uncertainties or limitations in the record. Transparent explanations are important because patient organizations and other stakeholders may need to help their communities understand what FDA's decision does and does not mean. This transparency is also important for maintaining confidence in a regulatory framework that must balance individualized access with appropriate safeguards.

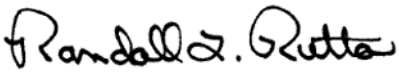
The NHC further encourages FDA to engage with patient organizations and other patient-centered stakeholders to better understand whether compounded products are being used by patients, how patients learn about them, whether patients understand the difference between compounded and FDA-approved products, what claims are being made in patient-facing materials, and whether patients are experiencing safety issues related to compounded products. Such input is not a substitute for clinical and scientific evidence, but it can help FDA identify real-world patient experience, communication gaps, and potential areas of risk that may not be visible through nominations, published literature, or adverse event reports alone.

Finally, the NHC cautions FDA to ensure that the decisions regarding nominated bulk drug substances do not inadvertently undermine incentives for appropriate evidence generation and product development intended to support FDA approval. Patients benefit when therapeutic approaches are studied through pathways that generate reliable evidence about safety, effectiveness, dosing, treatment effects, adverse events, and appropriate patient populations, and when FDA reviews such data and information. Compounding should not become a substitute for the development of evidence needed to support safe and effective FDA-approved therapies, particularly where products are being used for serious, chronic, or complex conditions and where broad or repeated use may pose unique patient safety considerations.

The NHC appreciates FDA's continued attention to the oversight of human drug compounding and encourages the Agency and the Pharmacy Compounding Advisory Committee to apply a patient-centered framework that protects patients from avoidable risks, unsupported therapeutic claims, unclear regulatory status, and inadequate evidence regarding safety, effectiveness, dosing, quality, and appropriate use. Please do not hesitate to contact Kimberly Beer, Senior Vice President, Policy & External Affairs, at kbeer@nhcouncil.org, or Shion Chang, Assistant Vice President, Policy & Regulatory Affairs, at schang@nhcouncil.org, if you or your staff would like to discuss these comments in greater detail.

We look forward to continuing to work with FDA to support policies that advance patient safety, evidence-based care, and meaningful access to therapies that meet patients' needs.

Sincerely,



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