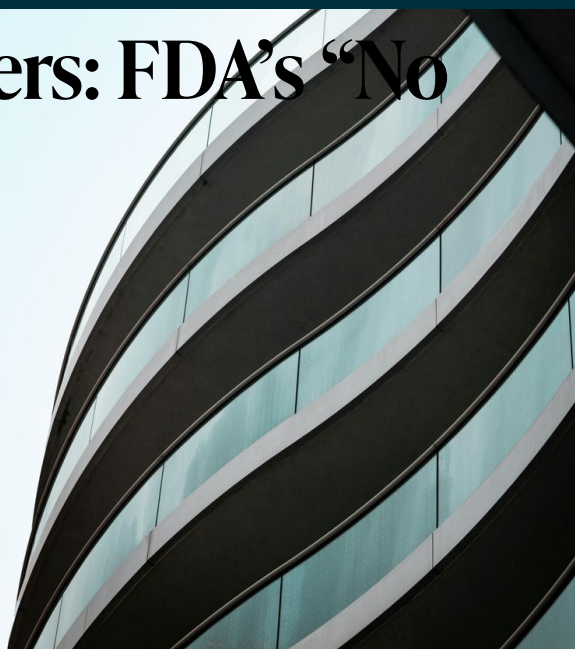
axinn

# Pounding the Compounders: FDA's "No Compound" Lists



3 MIN READ

February 16, 2025, 9:14 AM
By: Aziz Burgy, Sara Natour

Novo Nordisk recently made headlines petitioning FDA to stop the compounding of its blockbuster GLP-1 products so it can sell its patented semaglutide drugs exclusively. Compounding is the practice of creating new drug products through mixing, combining, diluting, reconstituting, or otherwise altering a drug or bulk drug substance.[1] Historically, healthcare facilities and pharmacies compounded customized medicine to suit patients' individual needs. Today, however, statutory and regulatory exemptions facilitate large-scale compounding comparable to drug manufacturing. FDA's 503A and 503B Bulks Lists evaluation process and Demonstrable Difficulties for Compounding (DDC) Lists promote consumer safety by foreclosing certain compounding activities.

**FDA Pathways to Prevent Commercial Compounding**

Sections 503A and 503B of the FD&C Act apply to compounding. Section 503A maps onto traditional pharmacy compounding (i.e., customizing drug products for individual patients). Meanwhile, Section 503B allows compounders to register as "outsourcing facilities" and produce drug products at scale in exchange for heightened reporting obligations and FDA inspection. Both 503A and 503B compounders remain exempt, however, from FDA's drug approval process and key regulatory safeguards.[2]

To temper risks flowing from regulatory exemptions, FDA delineates ingredients and drug products that are ineligible for compounding. Categories 2 and 3 of FDA's evaluation policy for the 503A and 503B Bulks Lists limit which ingredients compounders may use without the threat of anti-compounding enforcement. Likewise, the 503A and 503B DDC lists limit which drug products compounders may recreate. Both sets of lists promote consumer safety by precluding the circulation of dangerous and defective drug products. The Bulks Lists are currently in effect, and the DDC Lists are likely imminent per FDA's proposed rule of March 20, 2024.[3]

Bulks Lists

For nominations prior to January 7, 2025, FDA's 503A and 503B Bulks Lists evaluation policy delineates "bulk substances," or pharmaceutical ingredients, across three categories.[4] Category 1 lists ingredients that are insulated from anti-compounding enforcement due to a demonstrated clinical need for the ingredient and sufficient information supporting the compounded product's safety. Category 2 lists ingredients that are ineligible for compounding approval due to significant safety risks. Category 3 lists ingredients that are ineligible due to insufficient information supporting safety for compounding. For nominations both before and after January 7, 2025, interested parties may submit comments to FDA's docket regarding Bulks List approval.

DDC Lists

Like Category 2 of the Bulks Lists evaluation policy, the 503A and 503B DDC Lists indicate items that cannot be safely compounded. The DDC Lists, however, catalog drug products rather than pharmaceutical ingredients. FDA's proposed rule contemplates six criteria for the DDC Lists: (1) formulation complexity; (2) drug delivery mechanism complexity; (3) dosage form complexity; (4) complexity of achieving or assessing bioavailability; (5) compounding process complexity; (6) complexity of physiochemical or analytical testing. FDA deems drug products that have complex characteristics under these criteria to "present demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on safety or effectiveness." Compounders are thus prohibited from copying these drug products. While nascent, the DDC Lists might become an even more powerful resource in pharmaceutical companies' arsenal than the Bulks Lists evaluation process: wholesale preventing compounded drug products rather than slowing access to ingredients.

**Conclusion**

The Bulks Lists evaluation process and upcoming DDC Lists are two pathways for combatting compounder regulatory exemptions. In particular, the DDC Lists could wholesale block copying of certain drug products, though the contours of this regime are still developing.

—

[1] The term "bulk drug substance" is virtually interchangeable with active pharmaceutical ingredient (API).

[2] FDA safeguards from which compounders are exempt include the requirement that labels provide adequate directions for use.

[3] This proposed rule is Docket Number FDA-2023-N-0061.

[4] On January 7, 2025, FDA published Final Guidance modifying its evaluation policy for the 503A and 503B Bulks Lists. One significant change from this guidance is the elimination of the categories system for ingredients nominated after the Final Guidance's January 7, 2025 publication date.


## Related People

Aziz Burgy

Sara Natour

## Related Services

Intellectual Property

To subscribe to our publications, click here.

**TAGS**

pharma, regulatory

## News & Insights

- ABA 73rd Annual Section of Antitrust Law Spring Meeting
  **SPEAKING ENGAGEMENT** **ANTITRUST**
- CompLaw Nordic 2025
  **SPONSORSHIP** **ANTITRUST**
- GCR Live Cartels: 2025
  **SPEAKING ENGAGEMENT** **ANTITRUST**
- American Bar Association 2025 Asia-Pacific Conference
  **SPEAKING ENGAGEMENT** **ANTITRUST**
- Consumer Brands CPG Legal Forum 2025
  **SPEAKING ENGAGEMENT** **ANTITRUST**
- 2025 Why Antitrust: Everything You Need to Know About a Career in Antitrust Law

**SPEAKING ENGAGEMENT** **ANTITRUST**

- Competition Law Developments in Germany: Three Things We Are Watching
  **AXINN VIEWPOINTS** **ANTITRUST**

- Noerr Competition Day 2025
  **SPEAKING ENGAGEMENT** **ANTITRUST**

- Who's Blocking Me? Competition Law Issues With Healthcare Information Blocking
  **AXINN VIEWPOINTS** **ANTITRUST**

- Daniel Oakes, Tiffany Rider, and Lindsey Strang Aberg Win "Law360 Distinguished Legal Writing Award"
  **AWARDS & RECOGNITIONS** **ANTITRUST**