Session 4: Promoting compliance with the NDI notification requirement

Dr. Andrew Shao

Council for Responsible Nutrition

FDA Public Meeting

May 16, 2019

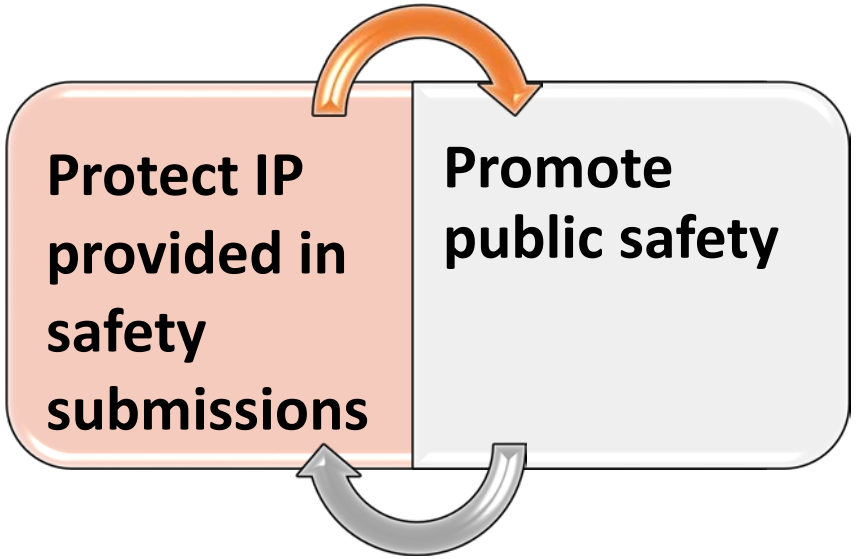
Strategies for promoting overall compliance with the NDI notification (NDIN) requirement

- Provide intellectual property protection
- Reduce the NDI notification burden
- Conduct meaningful, effective enforcement

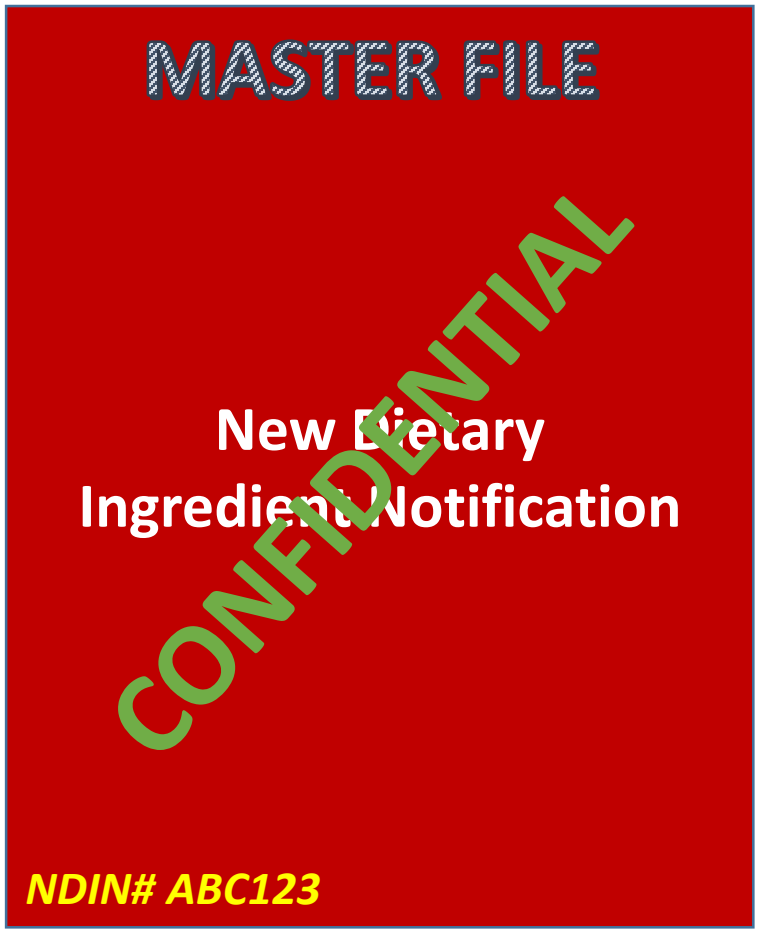
Provide intellectual property protection for safety data

Challenges:

- Lack of data protection (e.g., for demonstration of safety) is a disincentive to submit NDI notifications
- "Me too" imitators of branded ingredients come to market without any assurance of safety, relying on pirated data that may not relate to their ingredient
- FDA sees itself as first, and foremost, a protector of public safety—not a protector of intellectual property (IP) investments…*But these need not be mutually exclusive*
- Incentivizing more NDI notifications fosters better assurance that new ingredients, and products containing them, are safe
- Public safety can be served through IP protection



Protect intellectual property investments in the generation of safety data



Opportunity

- Incentivize ingredient manufacturers by vigorously protecting their investments in the generation of safety data
  - Establish NDI Master Files (NDIMF): a means of collecting and protecting data investments made by ingredient manufacturers specific to their products
  - NDIMF can be used/cited by subsequent filers (with permission)
  - Allow for referencing of NDIN# on labeling and marketing materials
  - **Vigorously defend/enforce the proper use of NDIMF to maintain integrity and utility**

IP *protection* ≠ *Exclusivity!*

Reduce the burden of NDIN submissions

Challenges:

- Misperception that every new dietary supplement contains a NDI and requires a separate notification
- For those that do contain a NDI, filing a NDIN for every unique formula is overly burdensome, provides little additional public protection, and creates a barrier to compliance with the NDI provision
- Industry is still not clear when a NDIN is required and what must be included in the submission

	1994	2019
Estimated # products in the US market	*≈ 4,000*	*≈ 80,000*

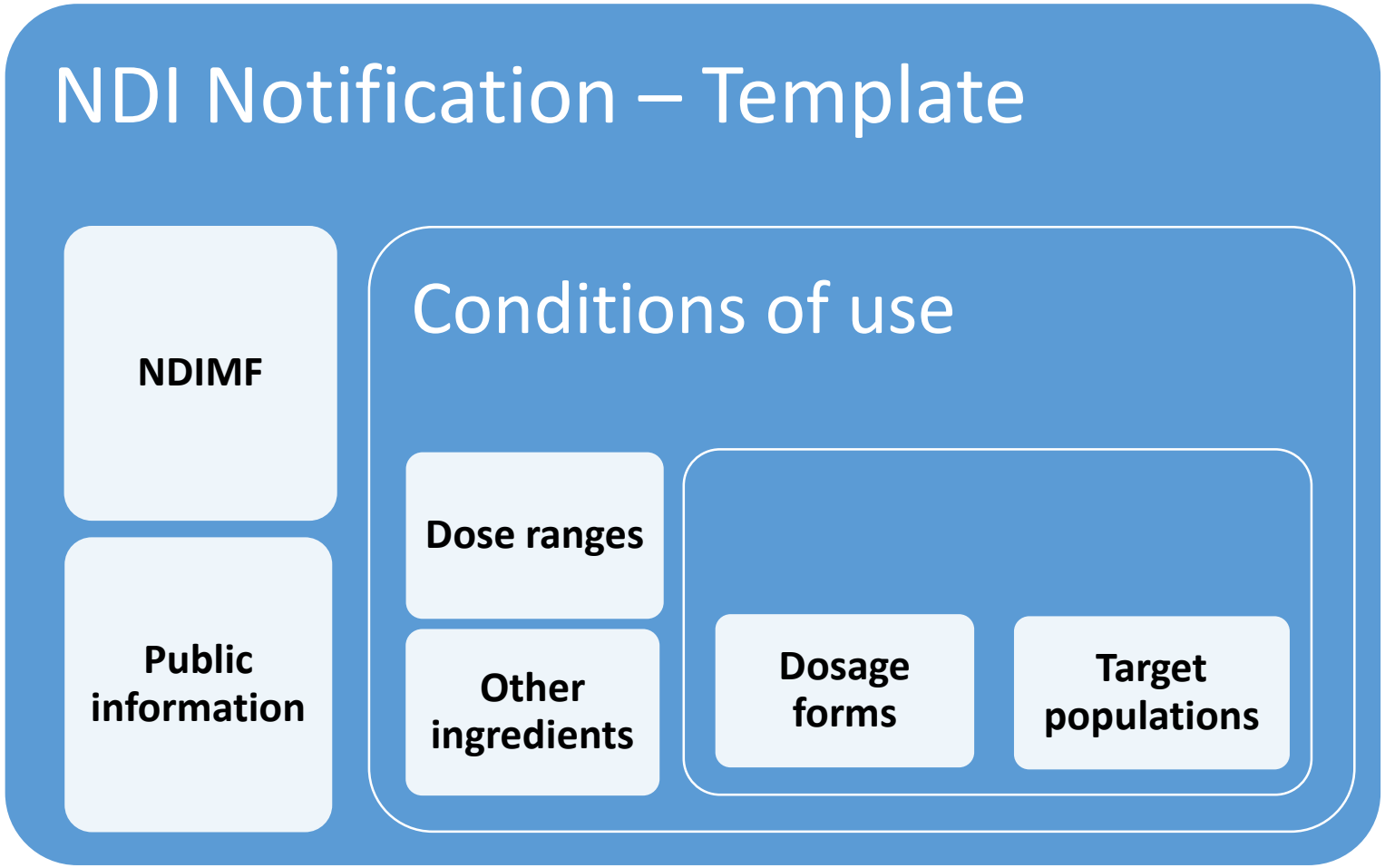
Vast majority of this growth has NOT come from NDIs

For those that do contain NDIs, duplicative finished products should not have to be notified if valid NDIN exists on file

Reduce the burden of NDIN

Opportunities:

- Permit ingredient manufacturers to determine the scope of their NDIN; they should establish a reasonable expectation of safety of the NDI under a range of conditions of use
- Render NDI requirements consistent with the GRAS process and address in the final NDI guidance
- Provide clarity in final guidance addressing requirements for NDINs to reduce objections due to lack of completeness



Meaningful, effective enforcement

Challenges

- Lack of perceived consequences for those who fail to comply with the NDI provision creates a disincentive for others to participate and contributes to confusion in the marketplace
- Limited resources at FDA require priority for safety issues (i.e., if it isn't perceived as affecting safety, it doesn't get addressed)
- Discovery of a pharmaceutical agent in a product results in referral to CDER for prosecution
- Perceived stakes of pursuing full investigation and prosecution discourage FDA legal action beyond warning letters

Meaningful, effective enforcement

Opportunity 1

- Use mandatory recall as a tool for enforcement
  - FDA has mandatory recall authority for foods (including dietary supplements) under FSMA
  - Products containing NDIs that have not been notified may be considered adulterated. *Note this is distinct from an NDIN submitted to FDA to which the agency has objected*
  - But FDA also has to establish SAHCODHA (serious adverse health consequences), which may be challenging for many NDIs

Meaningful, effective enforcement

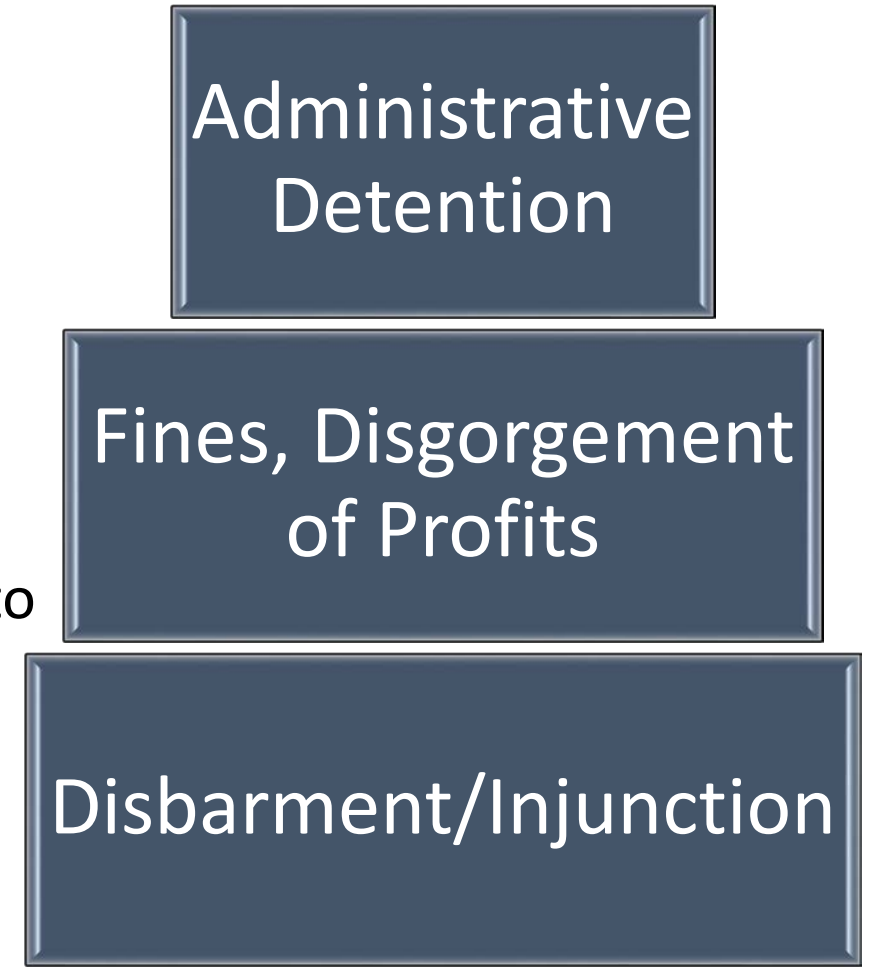
Opportunity 2

- Mandatory product listing
  - While not a cure-all solution, in concept, it would allow for easier identification of non-compliant products
  - ***But there must be consequences for failure to comply*** – a voluntary system, like the ***Supplement OWL***, is a worthwhile effort but not thoroughly effective without consequences for failure to list
  - FDA must be prepared with resources and resolve to address violators if a mandatory listing is created

Meaningful, effective enforcement

Opportunity 3

- FDA should utilize its other enforcement tools, including warning letters, untitled letters, seizure, and authority to initiate misdemeanor proceedings, to deter violations
- FDA should enforce through CFSAN all products that are represented to be dietary supplements (not refer them to CDER) for more consistent enforcement
- Work with state partners, such as state attorneys general, to increase enforcement activity
- FDA should request additional funding to ODSP



THANK YOU!