Session 4: Promoting compliance with the NDI notification requirement

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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
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New Dietary Ingredient Notification

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

<table>
<thead>
<tr>
<th>Estimated # products in the US market</th>
<th>1994</th>
<th>2019</th>
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<td>≈ 4,000</td>
<td>≈ 80,000</td>
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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 a 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!