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FDA Proposed Rule: *Nonprescription Drug Product with an Additional Condition of Nonprescription Use*

Consumer Healthcare Products Association

October 16, 2024

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Agenda

- Simultaneous Marketing Provision (Proposed 21 CFR §314.56(d))
- “Fail First” Provision (Proposed 21 CFR §314.56(c)(1)(vi))

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Durham-Humphrey Amendments

- A drug that can be used safely only "under the supervision of" a healthcare professional shall be dispensed only by prescription, and the drug's labeling must bear the symbol "Rx Only." FDCA § 503(b)(1), (b)(4)(A).
- A drug *not* subject to the prescription requirements "shall be deemed to be misbranded if at any time prior to dispensing the label of the drug bears the [Rx Only]" symbol. FDCA 503(b)(4)(B).
- The same drug therefore cannot simultaneously be both prescription and nonprescription.

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Case Study: MiraLAX Full Switch

- FDA completed a full prescription-to-nonprescription switch (switch of all approved uses) of PEG 3500 (MiraLAX) in 2008
- Before switch, abbreviated new drug applications (ANDAs or generics) had been approved for PEG 3500
- At the time of switch, then, there were both prescription and nonprescription versions of the same product on the market
- ANDA prescription products refused to exit market, and FDA initiated administrative process to revoke approvals

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MiraLAX Decision

- FDA found that because PEG 3500 switch was of all uses, the Rx ANDA and nonprescription products were the same drug
- By virtue of Durham-Humphrey, the Rx ANDA products therefore were misbranded and had to be removed from market
- FDA analysis turned on "meaningful differences" between the products: "indication, strength, route of administration, dosage form, [or] patient population." 83 Fed. Reg. 13994, 14000 (2018)

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MiraLAX Decision

- FDA rejected the argument that the very differences between prescription and non-prescription labeling necessary to accomplish a switch constitute a "meaningful difference" between two products
- FDA explained: "if FDA were to include the differences between prescription and nonprescription labeling requirements as a factor in determining whether there is a meaningful difference sufficient to allow the same active ingredient to be marketed in prescription and nonprescription products, *FDA would never be able to exempt a drug product from the prescribing requirements of Section 503(b).*" Id.

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ACNU Proposed Rule

- Contrary to language of statute and MiraLAX precedent, ACNU proposed rule states that *the ACNU itself* constitutes a "meaningful difference" between the prescription and nonprescription products, even if they have the same "indication, strength, route of administration, dosage form, [or] patient population."
- FDA gives no justification from this repudiation of the statute and FDA's longstanding position.

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Simultaneous Marketing is Bad Policy

- Innovation incentives
- Healthcare costs

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"Fail First" Provision

- Sponsor must provide "[a]dequate data or other information that demonstrates the necessity of the ACNU to ensure appropriate self-selection or appropriate actual use, or both"
- No objective standard set forth in regulations
- Need for ACNU may be evident
- Prolongs development programs