

In the
United States Court of Appeals
For the Seventh Circuit

Nos. 09-1438, 09-1462, 09-1601

SCHERING-PLOUGH HEALTHCARE PRODUCTS, INC.,

Plaintiff-Appellant/Cross-Appellee,

v.

SCHWARZ PHARMA, INC. and KREMERS URBAN, LLC,

Defendants-Appellees,

BRECKENRIDGE PHARMACEUTICALS, INC. and PADDOCK
LABORATORIES, INC.,

Defendants-Appellees/Cross-Appellants.

Appeals from the United States District Court
for the Eastern District of Wisconsin.

No. 2:07-CV-00642-JPS—**J.P. Stadtmueller**, Judge.

ARGUED SEPTEMBER 15, 2009—DECIDED OCTOBER 29, 2009

Before POSNER, FLAUM, and ROVNER, *Circuit Judges*.

POSNER, *Circuit Judge*. The parties to this Lanham Act suit are manufacturers of an oral laxative the chemical name of which is polyethylene glycol 3350. Schering, the

plaintiff, sells its version under the trade name “MiraLAX.” MiraLAX is an over-the-counter drug. The four defendants sell the generic version of the drug under its chemical name (except that defendants Kremers and Schwarz also use the name “GlycoLax”), but their version may be sold only if it is prescribed.

MiraLAX was originally a prescription drug too. After the patent on it expired, the Food and Drug Administration approved defendants’ ANDAs (Abbreviated New Drug Applications), which authorized them to sell a generic version of the drug. Later the FDA approved an over-the-counter version of MiraLAX but required that the label contain a warning to “use [for] no more than 7 days.” Constipation that lasts longer than that may be symptomatic of a serious medical condition, so a consumer who wants to use a laxative longer should do so under a doctor’s supervision.

The Food, Drug, and Cosmetic Act requires that the labeling of the generic drug be the same (with immaterial exceptions) as that of the original drug—the “pioneer” drug, as it is called, which in this case was the prescription-only version of MiraLAX. 21 U.S.C. § 355(j)(2)(A)(v); 21 C.F.R. § 314.127(a)(7). And if the generic drug is approved for use as a prescription drug, the label of the generic drug must “bear, at a minimum, the symbol ‘Rx only.’” 21 U.S.C. § 353(b)(4)(A). The labels of the defendants’ generic versions of MiraLAX do bear that symbol. The generic drug must also (though again with immaterial exceptions) be bioequivalent to the pioneer drug and have the same active ingredients, route of

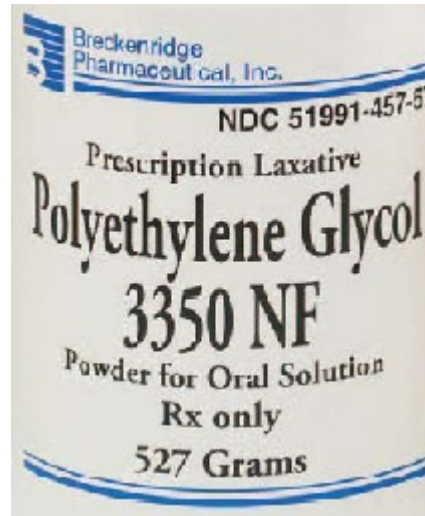
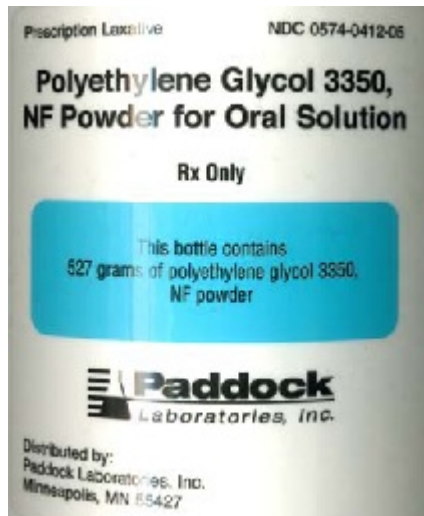
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administration, dosage form, and strength. 21 U.S.C. § 355(j)(2)(A); see *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990); *Andrx Pharmaceuticals, Inc. v. Elan Corp.*, 421 F.3d 1227, 1230-31 (11th Cir. 2005). There is no contention that the defendants' drugs fail to satisfy these requirements.

Section 43(a)(1)(B) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B), under which this suit was brought, forbids the use of any "false or misleading description of fact, or false or misleading representation of fact, which in commercial advertising or promotion, misrepresents the nature, characteristics, [or] qualities . . . of [the seller's] or another person's goods" There is no exemption for labels.

Schering argues that the labels, shown below, on the containers for the polyethylene glycol 3350 sold by the two principal defendants, Breckenridge and Paddock, are false. (The labels of the other two defendants' generics are similar, but the briefs focus on Breckenridge and Paddock.) The labels say that polyethylene glycol 3350 is sold only by prescription, whereas in fact, since over-the-counter MiraLAX by definition does not require a prescription, not *all* polyethylene glycol 3350 may be sold only by prescription. The statement in the label is repeated in the patient information that is included in the container in which the product is sold (the "package insert," which is deemed a part of the labeling of the product).

PADDOCK'S AND BRECKENRIDGE'S LABELS**PADDOCK'S AND BRECKENRIDGE'S
PATIENT INFORMATION INSERTS**

PATIENT INFORMATION Polyethylene Glycol 3350, NF Powder for Oral Solution is a prescription only laxative which has been prescribed by your physician to treat constipation.
PATIENT INFORMATION Polyethylene Glycol 3350 NF (Polyethylene Glycol 3350 Powder for Oral Solution) is a prescription only laxative which has been prescribed by your physician to treat constipation. This product should only be used by the person for whom it was prescribed.

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Although many prescription drugs are sold to the consumer in a plastic vial or other container supplied and relabeled by the pharmacist, polyethylene glycol 3350, whether sold by Schering or by the defendants, is sold to the consumer in its original container. This means that no one will see the labels on the defendants' product unless a physician has written a prescription for it, although one might see the label in an advertisement for the product. And should the patient's condition change, so that he didn't need to use a laxative for more than seven days, he might be unaware that he could switch to an over-the-counter version of the laxative that had been prescribed for him.

The FDA is conducting a proceeding to determine whether the defendants' drugs are misbranded now that there is an over-the-counter version of the drug. And because the Food, Drug, and Cosmetic Act does not permit both by-prescription-only and over-the-counter versions of the same drug to be sold at the same time, 21 U.S.C. § 355(b)(4); "Opportunity for Hearing on a Proposal to Withdraw Approval of Prescription Polyethylene Glycol 3350 Abbreviated New Drug Applications," 73 Fed. Reg. 63491, 63491-92 (FDA Oct. 24, 2008), the proceeding encompasses the issue of whether there is a "meaningful difference" between the pioneer drug and the generic drug or whether they are really "the same" drug. "Advance Notice of Proposed Rulemaking, Circumstances Under Which an Active Ingredient May Be Simultaneously Marketed in Both a Prescription Drug Product and an Over-the-Counter Drug Product," 70 Fed.

Reg. 52050, 52051 (FDA Sep. 1, 2005). The defendants argue that they are different drugs because their version is not subject to the 7-day warning.

If the FDA determines that they are “the same,” the result will be that the generic drug can no longer be sold, but even if it determines that they are different, it may decide that the labeling of the generics has to be changed. A drug is misbranded within the meaning of the Food, Drug, and Cosmetic Act “if its labeling is false or misleading in any particular,” 21 U.S.C. § 352(a), and Schering argues that the defendants’ labels occlude, in the mind of the consumer, the existence of its over-the-counter version of the drug. But maybe the FDA doesn’t care whether the labeling of the generic products obscures the existence of an over-the-counter equivalent; maybe all it cares about is that the labeling leads consumers to use the product safely, an objective that conceivably can be achieved just by making sure that doctors and pharmacists are accurately informed about the drug that they are prescribing, which of course is not the over-the-counter version. It is not obvious that the goal of protecting consumers is furthered by making sure that they are aware of the existence of an over-the-counter equivalent, and, if it is not, there would be no conflict between the FD&C Act and the Lanham Act. But we do not know, and see no need to guess while the misbranding proceeding is wending its way through the FDA.

The Director of the Office of Generic Drugs in the FDA’s Center for Drug Evaluation and Research wrote the defendants that their products are misbranded because

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the label says “Rx only” even though polyethylene glycol 3350 can also be sold without a prescription—thus MiraLAX. The letters are not final agency action. To rescind approval of the sale of a drug because of misbranding, the FDA must provide the manufacturer with “due notice and opportunity for hearing to the applicant.” 21 U.S.C. § 355(e). The agency is proceeding on that path, but no hearing has yet been scheduled, nor has the agency even decided whether a hearing will be necessary—it has as yet merely provided the participants with an opportunity to request a hearing. “Opportunity for Hearing on a Proposal to Withdraw Approval of Prescription Polyethylene Glycol 3350 Abbreviated New Drug Applications,” *supra*.

The district court dismissed the suit without prejudice, suggesting that Schering could refile it if and when the FDA decided that the defendants’ drugs were indeed misbranded. Schering has appealed, arguing that no reasonable trier of fact could fail to conclude that the terms “Rx only” and “a prescription only laxative,” which appear on the labels of the defendants’ drugs, are “literally false” and therefore violate the Lanham Act irrespective of the FD&C Act. And so it asks us to enter judgment in its favor rather than remand the case for evidentiary proceedings. The defendants have cross-appealed, contending that the suit should be dismissed with prejudice because Schering has no possible claim under the Lanham Act. They argue that a finding by the FDA that their products are not misbranded will mean that they are not falsely advertised, while if the agency finds that

the product is misbranded they will of course change the labeling to whatever the agency orders. This is an argument about mootness rather than about the merits, and not a good one, since it is merely speculation concerning what the defendants would do in response to a finding by the FDA of misbranding.

The defendants further suggest that the fact that the suit was dismissed without prejudice deprives us of appellate jurisdiction. The suggestion is made rather halfheartedly because they are strong for their cross-appeal, which argues that the dismissal should have been with prejudice. Making a dismissal without prejudice can be challenged by the winner (the defendant) because a litigant has a significant interest in the preclusive effect of a judgment in its favor. *Disher v. Information Resources, Inc.*, 873 F.2d 136, 138-39 (7th Cir. 1989); *LaBuhn v. Bulkmatic Transport Co.*, 865 F.2d 119, 121-22 (7th Cir. 1988); *H.R. Technologies, Inc. v. Astechologies, Inc.*, 275 F.3d 1378, 1381-82 (Fed. Cir. 2002). But the challenge can be mounted only if the dismissal is appealable. We have an independent duty to determine our jurisdiction, so the defendants' lack of enthusiasm for a dismissal of the appeal is not a ground on which we can disregard the issue.

There is no general rule that dismissals without prejudice are nonfinal orders and therefore nonappealable under 28 U.S.C. § 1291—if they were, dismissals for want of jurisdiction would not be appealable, and of course they are. *South Austin Coalition Community Council v. SBC Communications Inc.*, 191 F.3d 842, 844 (7th Cir. 1999). The

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typical case in which such a dismissal is nonfinal is a dismissal on the basis of an error that the judge expects will be corrected by the filing of an amended complaint. The judge thus has not finished with the case, and appeal would therefore be premature. *Hoskins v. Poelstra*, 320 F.3d 761, 763 (7th Cir. 2003); *Furnace v. Board of Trustees of Southern Illinois University*, 218 F.3d 666, 669-70 (7th Cir. 2000); *Ordower v. Feldman*, 826 F.2d 1569, 1572-73 (7th Cir. 1987); *Borelli v. City of Reading*, 532 F.2d 950, 951-52 (3d Cir. 1976) (per curiam); *B. Willis, C.P.A., Inc. v. BNSF Railway*, 531 F.3d 1282, 1296 n. 15 (10th Cir. 2008). But when the case does end in the district court, the dismissal is ripe for appeal even if a similar case may be filed in the future because the dismissal was without prejudice. *United States v. Wallace & Tiernan Co.*, 336 U.S. 793, 794-95 n. 1 (1949); *South Austin Coalition Community Council v. SBC Communications Inc.*, *supra*, 191 F.3d at 844; *Gray v. County of Dane*, 854 F.2d 179, 182 n. 4 (7th Cir. 1988); *Ohio River Co. v. Carrillo*, 754 F.2d 236, 238 (7th Cir. 1985) (per curiam); *Lichoulas v. City of Lowell*, 555 F.3d 10, 12-13 (1st Cir. 2009); *De Tie v. Orange County*, 152 F.3d 1109, 1111 (9th Cir. 1998); *Linn v. Chivatero*, 714 F.2d 1278, 1280 (5th Cir. 1983).

We grant that some opinions suggest that unless the plaintiff will be unable to bring a further suit in federal court (perhaps because the statute of limitations has run), a dismissal without prejudice is not appealable. E.g., *Doss v. Clearwater Title Co.*, 551 F.3d 634, 639 (7th Cir. 2008); *Mostly Memories, Inc. v. For Your Ease Only, Inc.*, 526 F.3d 1093, 1097 (7th Cir. 2008). But the holdings of those cases (as distinct from their dicta—statements inessential to the holdings) are consistent with the proposition that a

dismissal without prejudice is appealable unless the reason for the dismissal is an easily fixable problem; for the dismissals in those cases were found to be appealable even though they were without prejudice. Likewise in *South Austin* we concluded that “there was nothing tentative about the district court’s dismissal; no one is trying to achieve an interlocutory appeal without meeting the statutory requisites. This case has come to a close in the district court.” 191 F.3d at 844. *Ohio River* held that “though the dismissal order contemplates that appellant may eventually refile its admiralty complaint, the court, by dismissing the action, has terminated its jurisdiction over the original complaint. This is enough to render the order appealable.” 754 F.2d at 238. And in *Lichoulas*, 555 F.3d at 13, the court pointed out that dismissals for lack of ripeness are appealable, citing *Bateman v. City of W. Bountiful*, 89 F.3d 704, 705-06 (10th Cir. 1996), even though they are likely to be refiled at some future date—and the district judge in our case said he was dismissing it because it was unripe for decision.

In short, only if the defect that required dismissal is immediately curable is the dismissal nonappealable (though we are unclear why Schering did not ask for a preliminary injunction, the denial of which would have been appealable even if the dismissal was not, 28 U.S.C. § 1292(a)(1)). A dismissal without prejudice that is “conclusive in practical effect” is certainly appealable, as held in *American States Ins. Co. v. Capital Associates of Jackson County, Inc.*, 392 F.3d 939, 941 (7th Cir. 2004), but a dismissal without prejudice is not rendered unappealable merely by its not preventing the suit from being refiled.

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The judge did not stay the suit pending action by the FDA, as he might have done, *Cheyney State College Faculty v. Hufstедler*, 703 F.2d 732, 737-38 (3d Cir. 1983); cf. *Landis v. North American Co.*, 299 U.S. 248, 254-55 (1936) (Cardozo, J.); *American States Ins. Co. v. Capital Associates of Jackson Country, Inc.*, *supra*, 392 F.3d at 941; *Tice v. American Airlines, Inc.*, 288 F.3d 313, 317-18 (7th Cir. 2002), by analogy to the doctrine of primary jurisdiction. *United States v. Western Pacific R.R.*, 352 U.S. 59, 63-64 (1956); *In re StarNet, Inc.*, 355 F.3d 634, 639 (7th Cir. 2004); *Arsberry v. Illinois*, 244 F.3d 558, 563-64 (7th Cir. 2001). Such a stay would not have been appealable unless its practical effect was to end, not merely interrupt, the judicial proceeding, as in *Moses H. Cone Memorial Hospital v. Mercury Construction Corp.*, 460 U.S. 1, 10 (1983). The stay issued in *Cone* was in favor of a state-court proceeding, the final judgment in which would operate as res judicata in the federal proceeding. The Court held that a stay is appealable if it has the same effect as a dismissal that would be appealable; for it is the effect of a judicial order, rather than what the judge calls it, that matters in determining appealability.

Primary jurisdiction, as we explained in the *Arsberry* case, sometimes involves reference of an issue to an agency that has exclusive jurisdiction to resolve it. If the issue is dispositive and its resolution by the agency is reviewable in another court, the case will never return to the referring court and therefore a stay of the initial judicial proceeding to permit the reference would have the same effect as a dismissal. But as we noted earlier, it

is unclear whether that will be the result when the FDA completes its misbranding proceeding.

We turn at last to the merits. We can set aside the letters from subordinate officials of the FDA; the letters are not final agency action binding on the district court, as there has been no final agency action, let alone action that has been or could be judicially reviewed. We can also set aside any argument that the defendants' drugs are misbranded because they are labeled prescription drugs—they *are* prescription drugs, so their labels *have* to say that, even if a close substitute (over-the-counter MiraLAX) is not. Schering tacitly concedes this, and just argues that the labels need a disclaimer indicating that not *all* drugs of which polyethylene glycol 3350 is the active ingredient require a prescription.

Nor do we think that just because the provision of the Lanham Act on which Schering's suit is based is intended to protect competitors from the effects of false advertising or labeling, while the misbranding provision of the Food, Drug, and Cosmetic Act is intended to protect the consumers of drugs, *Sandoz Pharmaceuticals Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 230 (3d Cir. 1990), there can be no conflict between the statutes, hence no occasion for delaying this litigation to allow the FDA to weigh in. A disclosure required to protect a competing seller might mislead a consumer, in which event the drug would be mislabeled and could not be sold, so that the seller's concern with unfair competition would be moot; it would have no competitor because there would be no competing product. The case would be

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like *SmithKline Beecham Consumer Healthcare, L.P. v. Watson Pharmaceuticals, Inc.*, 211 F.3d 21 (2d Cir. 2000), where copyright law would have forbidden a manufacturer of a generic drug to copy the pioneer manufacturer's labels, but failing to copy them would have violated the requirement of the FD&C Act that the label of a generic drug be the same as the pioneer's label, and so would have precluded generic manufacturer from legally marketing its product. The court resolved the conflict by allowing the FD&C Act's labeling requirement to trump copyright law. See also *Zenith Electronics Corp. v. Exzec, Inc.*, 182 F.3d 1340, 1347, 1352-54 (Fed. Cir. 1999); *Vornado Air Circulation Systems, Inc. v. Duracraft Corp.*, 58 F.3d 1498, 1507-10 (10th Cir. 1995).

Courts try to give as much effect to both statutes as possible, and in that vein Schering argues that the FD&C Act shouldn't be interpreted to forbid the defendants to make a disclaimer that would cure the misrepresentation upon which Schering's Lanham Act suit is predicated. But Schering has been coy about what it thinks the disclaimer should say, and its coyness makes us doubt that this is a matter that can be resolved intelligently without a decision by the FDA. At argument Schering's lawyer seemed to concede that if the defendants' labels said "Paddock's Polyethylene Glycol 3350, Rx Only" and "Breckenridge's Polyethylene Glycol 3350, Rx Only," it would be content. Its briefs do not propose a wording, however, and we hesitate to hold a lawyer to a concession made in the heat of oral argument in response to rapid-fire questions from the bench.

We can imagine the FDA worrying that the wording that Schering's lawyer suggested at the argument would make some consumers think that only Paddock's or only Breckenridge's polyethylene glycol 3350 is prescription only, or would make consumers wonder whether the two brands might be chemically different products. The FDA should be given a chance to opine on the proper labeling before a Lanham Act suit is filed, *Sandoz Pharmaceuticals Corp. v. Richardson-Vicks, Inc., supra*, 902 F.2d at 230-31; compare *Alpharma, Inc. v. Pennfield Oil Co.*, 411 F.3d 934, 937-39 (8th Cir. 2005), since it has more experience with consumers' understanding of drug labels than judges do. *Alpharma*, in contrast, was a case in which the complaint under the Lanham Act was simply that the defendant had said that the FDA had approved its drug for a number of uses for which it had not been approved. Evaluating such a charge did not draw on the agency's insights into the understanding of consumers of drugs; allowing the suit to proceed without reference to the agency was therefore not objectionable as an attempt to use the Lanham Act as a vehicle for enforcing the Food, Drug, and Cosmetics Act, which does not authorize a private cause of action. *Sandoz Pharmaceuticals Corp. v. Richardson-Vicks, Inc., supra*, 902 F.2d at 231; *Mylan Laboratories, Inc. v. Matkari*, 7 F.3d 1130, 1139 (4th Cir. 1993); cf. *Dial A Car, Inc. v. Transportation, Inc.*, 82 F.3d 484, 488-90 (D.C. Cir. 1996); *Cottrell, Ltd. v. Biotrol International, Inc.*, 191 F.3d 1248, 1254-55 (10th Cir. 1999).

Or suppose the label on the container of Paddock's polyethylene glycol 3350 had said that it was the only

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polyethylene glycol 3350 that won't make hair grow on the palm of your hand, or that each container contains 727 grams of the drug, when in fact it contains only 527 grams, like its competitors' containers. As in the *Alpharma* case, there would be no need to delay the Lanham Act suit to await the outcome of an FDA hearing on misbranding. Cf. *Cottrell, Ltd. v. Biotrol International, Inc.*, *supra*, 191 F.3d at 1254-57; *Marriott Corp. v. Great America Service Trades Council*, 552 F.2d 176, 180-81 (7th Cir. 1977). This case is subtler, however, because it is unclear how the "Rx only" representations on the containers are understood by consumers and how a disclaimer should be worded to improve that understanding.

Schering invokes regulations under the FD&C Act that allow the seller of a drug to make "a change in the labeling concerning the description of the drug product or in the information about how the drug product is supplied, that does not involve a change in the dosage strength or dosage form," 21 C.F.R. § 314.70(d)(2)(ix), and "an editorial or similar minor change in labeling." 21 C.F.R. § 314.70(d)(2)(x). In neither case must the seller obtain the agency's approval, though it must notify the agency of the change. These are what are called "minor changes." "Moderate changes"—changes that strengthen warnings or delete false, misleading, or unsupported indications for use or claims for effectiveness—also don't require pre-approval. 21 C.F.R. § 314.70(c)(6)(iii). But a supplemental application must be filed, and the FDA can disapprove the application and order the manufacturer to stop distributing the drug with the change.

“Major” changes, described at length in 21 C.F.R. § 314.70(b)(2)(v), require pre-approval. (The tripartite scheme is described in *Wyeth v. Levine*, 129 S. Ct. 1187, 1196 (2009), and *Colacicco v. Apotex, Inc.*, 521 F.3d 253, 259 (3d Cir. 2008), vacated on other grounds, 129 S. Ct. 1578 (2009).) “Major” changes are the residual category, because they are defined to include “changes in labeling except those described in” the provisions dealing with minor and moderate changes. 21 C.F.R. § 314.70(b)(2)(v)(A). “Any proposed change in the labeling, except changes designated as moderate or minor by regulation or guidance, must be submitted as a prior approval supplement.” FDA Center for Drug Evaluation and Research, “Guidance for Industry: Changes to an Approved NDA or ANDA, Revision 1” 24 (2004), www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm077097.pdf (visited Oct. 8, 2009). Just to confuse matters, minor changes are said to “include, *but are not limited to* [a list of 10 changes, of which (ix) and (x) refer to labeling changes].” 21 C.F.R. § 314.70(d)(2) (emphasis added). But it makes more sense to regard major changes as the residual category, as otherwise the regulations would have a dangerous loophole.

So the changes Schering wants the defendants to make in their labeling, since they do not fit the definitions of minor or moderate changes, are major changes, requiring the FDA’s approval. This inference is strengthened by the fact that the FDA would probably want to require pre-approval of a disclaimer that might mislead consumers. Otherwise it might take years for the agency to get around to prohibiting a misleading label.

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A further complication arises from the requirement that the label of a generic drug must be the same as that of the pioneer drug. Does this mean that the “changes” regulations have no application to generic labeling? That seems hardly likely, but to our surprise this appears to be an open question. One case suggests that the regulations are applicable to generic labeling, *Foster v. American Home Products Corp.*, 29 F.3d 165, 169-70 (4th Cir. 1994), but in a footnote to a recent proposal to amend the regulations the FDA said that “CBE changes are not available for generic drugs approved under an ANDA under 21 U.S.C. § 355(j).” 73 Fed. Reg. 2848, 2849 n. 1 (Jan. 16, 2008). CBE changes (“Changes Being Effected”) are in the “moderate” category, which may be implemented upon the agency’s receiving a supplemental new drug application that documents the changes. It isn’t clear whether the FDA was referring in the footnote to *all* changes that a generic manufacturer might make to its labels, but if it applies to moderate changes presumably it applies to major ones as well. Fortunately, the issue need not be resolved to decide this appeal.

We agree with the district court, therefore, that Schering jumped the gun by suing before the FDA addressed the misbranding issue. We think there is force, too, to the defendants’ contention that the district court was correct to deny Schering’s motion for partial summary judgment on its Lanham Act claim regardless of how the FDA rules. Schering argues that the defendants’ labels contain a “literally false” statement, and invokes cases that say that a plaintiff who can prove that the defendant’s advertising or labeling is “literally false” is entitled to

judgment even though it has no evidence that anyone was misled. *Avila v. Rubin*, 84 F.3d 222, 227 (7th Cir. 1996); *Abbott Laboratories v. Mead Johnson & Co.*, 971 F.2d 6, 13-14 (7th Cir. 1992); *Time Warner Cable, Inc. v. DIRECTV, Inc.*, 497 F.3d 144, 153 (2d Cir. 2007); *Castrol Inc. v. Pennzoil Co.*, 987 F.2d 939, 943 (3d Cir. 1993); *Allsup, Inc. v. Advantage 2000 Consultants, Inc.*, 428 F.3d 1135, 1138 (8th Cir. 2005).

As far as we know, the only consumers who see the labels and package inserts in the defendants' polyethylene glycol 3350 drugs are persons who have been prescribed the generic drug by a physician. Maybe they saw the warning on the over-the-counter MiraLAX and decided to consult a physician rather than buy the over-the-counter product and he prescribed the generic—he knows there's an over-the-counter product that contains the same active ingredient but he decided to go the prescription route with this patient. Or someone might see the defendants' products on the shelf in a pharmacy and go running to his physician. But if the physician thought the patient would do fine with the over-the-counter drug, he would presumably suggest that drug to the patient.

Prescription drugs are sometimes advertised, but Schering does not complain about the advertising by the defendants, and the advertisement for Breckinridge's drug, posted on its website, contains just the sort of disclaimers that Schering is seeking:

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*Breckenridge Pharmaceutical, Inc.
continues to market
Polyethylene Glycol 3350 NF
Powder for Oral Solution
under the original
ANDA's approved Rx version.*



**Still Available
by Prescription**

See full prescribing
information on back.

Prescription ("Rx") uses of Polyethylene Glycol 3350 Powder for Oral Solution ("PEG") remain approved and necessary. The FDA has concluded that Over the Counter ("OTC") use of PEG is only appropriate for "no more than 7 days," which is consistent with historic OTC drug use, and has approved an NDA for this OTC use. For laxative use of PEG longer than 7 days, a physician's intervention and prescription is required.

For different conditions of use or indications, the FDA does permit the same active ingredient with the same dosage but different labeling (i.e., dosing regimens) to exist as both Rx and OTC (e.g., Ranitidine HCl 150mg/ Zantac® 150mg).

Our Rx generic PEG is subject to an approved ANDA and has a unique, Rx-only dosing regimen (with FDA-mandated labeling) that is significantly different from the newly created OTC version. Our Rx version, approved under a separate ANDA, has been and remains medically appropriate. Therefore, our PEG product continues to be lawfully marketed.

For more information on our products,
contact your wholesaler or distributor
or visit us at www.bpire.com.

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**Breckenridge
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At any rate, whether our speculation about the effect of the labels on consumer choice is right or wrong, Schering has made no attempt to prove that anyone was misled, because it thinks that all it needs to show is “literal falsity.”

This is an unfortunately common example of a litigant misled by general language in judicial opinions. Opinions would be even longer than they are if judges couldn’t use short phrases to denote what may be complex legal doctrines. When those phrases are taken to be exhaustive statements of entire doctrines with all necessary qualifications, the result is likely to be a misapprehension of the law. William Blake declared that “to Generalize is to be an Idiot. To Particularize is the Alone Distinction of Merit.” That is a bit extreme; but uncritical generalization is a path to error. One form of uncritical generalization, ironically in view of Schering’s invocation of the doctrine of “literal falsity,” is reading general language literally.

The purpose of the false-advertising provisions of the Lanham Act is to protect sellers from having their customers lured away from them by deceptive ads (or labels, or other promotional materials). Many literally false statements are not deceptive. When the Soviet Union in the 1930s declared that “ $2 + 2 = 5$,” it was not deceiving anyone; it was announcing a slogan designed to spur workers to complete the Five-Year Plan in four years. If one opened the *New York Times* “literally” at random one might find an ad that calls Graff Diamonds “The Most Fabulous Jewels in the World.” That is literally false because the jewels sold by Graff are no more fabulous than, say, the Crown Jewels of England, or the Hope Diamond.

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But no one is deceived, so there is no injury, and a suit by a competitor of Graff would fail. See *Time Warner Cable, Inc. v. DIRECTV, Inc.*, *supra*, 497 F.3d at 159-61; *Johnson & Johnson * Merck Consumer Pharmaceuticals Co. v. Smithkline Beecham Corp.*, 960 F.2d 294, 298 (2d Cir. 1992); *Castrol Inc. v. Pennzoil Co.*, 987 F.2d 939, 945 (3d Cir. 1993); *Pizza Hut, Inc. v. Papa John's International, Inc.*, 227 F.3d 489, 496-97 (5th Cir. 2000); *United Industries Corp. v. Clorox Co.*, 140 F.3d 1175, 1180 (8th Cir. 1998); cf. *Muha v. Encore Receivable Management, Inc.*, 558 F.3d 623, 627 (7th Cir. 2009). The cases that reject liability do so in the name of “puffery”—meaningless superlatives—but the principle cuts deeper; if no one is or could be fooled, no one is or could be hurt. Cf. *Hahn v. Triumph Partnerships LLC*, 557 F.3d 755, 757-58 (2009); *Wahl v. Midland Credit Management, Inc.*, 556 F.3d 643, 645-46 (7th Cir. 2009).

The other side of this coin is that a representation may be so obviously misleading that there is no need to gather evidence that anyone was confused. See, e.g., *Abbott Laboratories v. Mead Johnson & Co.*, *supra*, 971 F.2d at 13-14; *PPX Enterprises, Inc. v. Audiofidelity Enterprises, Inc.*, 818 F.2d 266, 271-73 (2d Cir. 1987). And it is often clearer that a claim is misleading than that it is literally false, because what is “literally” false is often a semantic question.

What the cases mean when they say that proof of literal falsity allows the plaintiff to dispense with evidence that anyone was misled or likely to be misled is that the seller who places an indisputably false statement in his advertising or labeling probably did so for a malign purpose, namely to sell his product by lies, and if the

statement is false probably at least some people were misled, and since it was a lie why waste time on costly consumer surveys? See *PPX Enterprises, Inc. v. Audiofidelity Enterprises, Inc.*, *supra*, 818 F.2d at 272-73; *Castrol Inc. v. Pennzoil Co.*, *supra*, 987 F.2d at 951 (dissenting opinion). When this is stated as the doctrine of “literal falsity,” “literal” must be understood in the common colloquial sense in which Americans (not realizing, or perhaps not caring, that they are making Fowler turn in his grave) say things like “I am literally out of my mind.” A “literal” falsehood is bald-faced, egregious, undeniable, over the top.

We *know* this is what the cases are driving at because they add to “literal falsity” such qualifiers as that the meaning of the alleged literal falsehood must be considered in context and with reference to the audience to which the statement is addressed. *Avis Rent A Car System, Inc. v. Hertz Corp.*, 782 F.2d 381, 385-86 (2d Cir. 1986) (Friendly, J.) (“fundamental to any task of interpretation is the principle that text must yield to context”); see also *Castrol Inc. v. Pennzoil Co.*, *supra*, 987 F.2d at 946-47; *Pizza Hut, Inc. v. Papa John’s International, Inc.*, *supra*, 227 F.3d at 495 n. 5; *Southland Sod Farms v. Stover Seed Co.*, 108 F.3d 1134, 1139 (9th Cir. 1997). That is how one obtains an understanding of the real meaning of “2 + 2 = 5” in Soviet propaganda.

The proper domain of “literal falsity” as a doctrine that dispenses with proof that anyone was misled or likely to be misled is the patently false statement that means what it says to any linguistically competent person, unlike the

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examples we have given. So suppose the labels on the defendants' products stated: "All polyethylene glycol 3350, by whomever made, can be sold only by prescription; there is no over-the-counter version of this drug." That would be false and misleading per se; there would be no need to consider context or audience.

But that is not what the labels say. There is no statement in the ordinary sense, because there is no verb. There is the manufacturer's name at the top, the name of the active ingredient, the symbol "Rx only," and some other information. Obviously *this* product, the product of the named manufacturer, is prescription only, but it is not obvious, as Schering contends, either from the labels or from the package inserts (which say "Polyethylene Glycol 3350 NF Powder for Oral Solution is a prescription only laxative which has been prescribed by your physician to treat constipation"), that every other product containing polyethylene glycol 3350 is prescription only. Schering cannot just intone "literal falsity" and by doing so prove a violation of the Lanham Act. But we think the district court was right nevertheless not to dismiss the suit with prejudice; findings by the FDA in the misbranding proceeding may cast the issue of consumer confusion in a different light.

AFFIRMED.