



December 20, 2002

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20852

Re: Proposed Rule - Applications for FDA Approval to Market  
a New Drug: Patent Listing Requirements and Application  
of 30-Month Stays on Approval of Abbreviated New Drugs  
Applications Certifying That a Patent Claiming a Drug is  
Invalid or Will Not be Infringed

Dear Madam or Sir:

GlaxoSmithKline (GSK) is a world leading research-based pharmaceutical company engaged in the creation, discovery, development, manufacture, and marketing of pharmaceutical and consumer health-related products. The Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act") greatly impacted the intellectual property rights of pioneer pharmaceutical firms such as GSK. The culmination of years of legislative consideration and debate, the Hatch-Waxman Act is at base a compromise, balancing the conflicting objectives of preserving incentives for pioneer firms to make the necessary expenditures to research and develop new drugs while simultaneously facilitating the ability of competing firms to bring less expensive, generic versions of these drugs to market. *See Mylan v. Thompson*, 268 F.3d 1323, 1326 (Fed. Cir. 2001). The regulations implementing the Hatch-Waxman Act have a major effect on the balance between these competing objectives. Any regulatory proposal to amend these regulations thus has the potential to alter incentives for pioneer pharmaceutical companies, such as GSK, to dedicate the necessary resources to the research and development of new drugs.

On October 24, 2002, the Food and Drug Administration ("FDA" or "Agency") proposed changes in its Hatch-Waxman regulations, specifically those governing the listing of patents in its publication "Approved Drug Products with Therapeutic Equivalence Evaluations" ("the Orange Book") and the availability and operation of the statutory stay that prevents the Agency from finally approving an ANDA or 505(b)(2) application for thirty months after an NDA or patent holder files a patent infringement suit against the applicant. 67 Fed. Reg. 65448 (Oct. 24, 2002) (to be codified at 21 C.F.R. § 314) (hereinafter referred to as the "Notice" for the discussion and the "Proposed Rule" for the proposed regulation). The ability of pharmaceutical patent holders to list their patents in the Orange Book and thus, in certain circumstances, obtain a

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30-month stay is an integral part of the Hatch-Waxman compromise. These provisions are rooted in the fact that the Hatch-Waxman Act deprived pharmaceutical patent holders of certain rights available to all other patent holders -- namely, the right to prevent certain infringing uses during the patent term. In addition, the Act deprived the pharmaceutical companies of their exclusive rights in confidential commercial information by allowing generic companies to rely on the innovator's data, gathered at great expense, after as little as four years<sup>1</sup> -- where such proprietary information had been previously protected against disclosure or use forever.

Specifically with respect to patents, pursuant to the "Bolar Amendment," 35 U.S.C. § 271(e)(1), pharmaceutical patent holders lost the right to prevent the making, using, or selling of their patented product, during the patent term, by would-be ANDA filers for purposes of obtaining FDA approval. 21 U.S.C. § 271(e)(1). As part of the exchange for giving up those rights, pioneer manufacturers were, through the operation of the Orange Book listing and 30-month stay provisions, to be afforded the opportunity to resolve patent disputes prior to the approval and market entry of potentially infringing generic products. *See* H. Rep. 98-857 pt. 1 at 27-28 (June 21, 1984).

FDA must remain mindful of this delicate balance as it considers enacting its Proposed Rule. GSK is concerned that the Proposed Rule threatens this balance and would unfairly tip the scales in favor of the generic industry, and supports the comments submitted by the Pharmaceutical Research and Manufacturers of America. Additionally, GSK takes this opportunity to comment on several issues raised in the Notice and Proposed Rule in which it has a unique interest.

First, GSK objects to FDA's characterization of the representations GSK made in connection with the patent listing dispute involving its drug Paxil® (paroxetine hydrochloride). Second, while GSK agrees with FDA that patents claiming different forms of the active ingredient than found in the marketed product should be listed in the Orange Book, it takes issue with FDA's description of this position as a "change in [its] patent listing policy." 67 Fed. Reg. at 65452. As aptly illustrated by the Paxil dispute, FDA policy currently provides for the listing of such patents. Accordingly, FDA must clarify that this is not in fact a policy change. Third, GSK believes there is no reason why a good faith patent listing should estop a patent holder from objecting to ANDA eligibility or advocating that additional data be presented for a determination of sameness. Fourth, GSK does not believe that a requirement for claim-by-claim listing is appropriate or consistent with the statute. Fifth, GSK agrees that product by process patents are appropriately listable. Sixth, GSK believes that patents covering devices or containers

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<sup>1</sup> Four years after a product is approved under 505(b), a generic company may submit an ANDA relying upon the innovator's proprietary safety and efficacy data for approval if the ANDA is accompanied by a paragraph IV certification challenging a patent listed in the Orange Book. 21 U.S.C. § 355(j)(5)(D)(ii). If unaccompanied by a patent challenge, such ANDA may be submitted for approval after 5 years. *Id.*

that are integral parts of the drug delivery system should be listable. Finally, should FDA ultimately amend its regulations governing the 30-month stay, it must only apply the new regulations prospectively to NDAs and patents filed after the effective date so as to not disturb pending litigation or the vested rights of NDA holders.

**1. GSK's Response To the Apotex Citizen Petition Properly Represented The Claims Of The Disputed Patents.**

Pursuant to the Agency's current patent listing regulations, an NDA holder or applicant is required to submit information on

each patent that claims the drug or a method of using the drug that is the subject of the new drug application or amendment or supplement to it and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product.

21 C.F.R. § 314.53(b). According to the Agency, its "longstanding" interpretation of "drug" in this context refers to "the approved drug product." 67 Fed. Reg. at 65449. In discussing this interpretation, FDA makes specific reference to a dispute involving patents listed in association with GSK's Paxil.

There, Apotex filed a citizen petition requesting that the Agency de-list two patents claiming anhydrate forms of paroxetine hydrochloride. The listed drug for Paxil is paroxetine hydrochloride. Orange Book 3-271 (22nd ed. 2002). Paxil, as marketed, contains paroxetine hydrochloride in a hemihydrate form. Apotex alleges that its active ingredient is paroxetine hydrochloride which it asserts to be in the anhydrate form. Nevertheless, Apotex submitted a certification with the filing of its ANDA stating that its product contained the "same" active ingredient as Paxil. *See* 21 U.S.C. § 355(j)(2)(A)(ii)(I). Apotex then argued that the patents did not claim GSK's marketed drug, and that the marketed drug should be considered the listed drug. In fact, if the marketed drug (paroxetine hydrochloride hemihydrate) was the listed drug, the FDA should not have accepted Apotex's ANDA in the first place.

According to FDA, it relied on GSK's "representations that the patent claimed the approved drug product" and thus "concluded that the patents had been correctly submitted for listing." 67 Fed. Reg. at 65451. GSK is concerned that this statement falsely implies that GSK somehow represented that its patents claimed something they did not. In fact, GSK from the start unambiguously informed FDA that the listed patents claimed a different crystalline form than that marketed in Paxil. GSK's certification accompanying the request to list the anhydrate patent stated "The following patent covers paroxetine hydrochloride anhydrate, which under current FDA policy is considered 'the same active ingredient' as paroxetine hydrochloride

hemihydrate, the active ingredient of *Paxil* (paroxetine hydrochloride)." Moreover, when Apotex submitted its ANDA, it asserted that its product contained the "same" active ingredient as *Paxil*. Indeed, that assertion was a necessary condition of Apotex being able to submit an ANDA, because an ANDA product must contain the "same" active ingredient as the reference listed drug. 21 U.S.C. § 355(j)(2)(A)(ii)(I); 21 C.F.R. § 314.92(a)(1).

After Apotex filed its petition, GSK filed a response with the FDA in which it set forth, among other things, its case that the patents were properly listed: "the active ingredient is paroxetine hydrochloride, and these patents claim paroxetine hydrochloride; the hemihydrate and anhydrous forms of paroxetine hydrochloride are considered by FDA and asserted by Apotex to be the same; and the relevant court cases support listing."<sup>2</sup> GSK was forthright that "paroxetine hydrochloride is present in *Paxil* in a particular polymorphic or crystalline form known as 'hemihydrate,' while the patents cover different forms known as the 'anhydrous' forms A and C."<sup>3</sup> GSK, however, asserted that because the patents claim the drug substance as defined by FDA (and as asserted by Apotex), i.e., paroxetine hydrochloride, they were required to be listed.<sup>4</sup> As FDA's ultimate decision demonstrates, the Agency agreed.

The Agency correctly stated in the Notice that "patents must be listed if they claim the drug substance or active ingredient of an approved drug product, or if they claim the drug substance that is the component of such a product." Moreover, the relevant case law has supported the listing of patents claiming alternative crystalline forms of the active ingredient of the approved drug product. *See Zenith Labs., Inc., v. Abbott Labs.*, No. 96-1661, 1996 WL 33344963 (D.N.J. Aug. 7, 1996); *Ben Venue Labs., Inc. v. Novartis Pharm. Corp.*, 10 F. Supp. 2d 446 (D.N.J. 1998). In *Zenith*, the district court denied a generic manufacturer's request to compel an NDA holder to de-list patents claiming anhydrous forms of the active ingredient, terazosin hydrochloride, which was used in the approved drug product in the dihydrate form. Similarly, in *Ben Venue*, the court approved the listing of a patent claiming an alternative crystalline form of the active ingredient, even though that form did not appear in the finished dosage form. These cases provided a reasonable basis for GSK's submission of its patents claiming paroxetine hydrochloride anhydrate for listing in the Orange Book. Thus the Agency's correct conclusion that anhydrate and hemihydrate forms of drug substances are pharmaceutical equivalents and, therefore, contain the same active ingredient, is fully consistent with GSK's claim that patents covering either polymorph are listable as claiming the active ingredient of an approved drug product. Accordingly, GSK requests that FDA correct the misimpression that GSK asserted that the listed anhydrate patents claimed paroxetine hydrochloride hemihydrate,

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<sup>2</sup> Letter from Bruce N. Kuhlik to Documents Management Branch, June 13, 2000 (Docket No. 00P-0499/CP1), at 5.

<sup>3</sup> *Id.* at 6.

<sup>4</sup> *Id.*

and acknowledge that its decision was predicated upon a knowledge that the patents claimed paroxetine hydrochloride anhydrate.

**2. FDA's Proposed Rule Allowing For The Submission Of Information On Patents Claiming Alternate Crystalline Forms Is Consistent With And Not A Change From FDA's Prior Policy**

The Proposed Rule would allow NDA holders to submit information on patents claiming "a drug substance that is the same as the active ingredient that is the subject of the approved or pending application within the meaning of section 505(j)(2)(A)(ii) of the Act." 67 Fed. Reg. at 65451. FDA contends that this would be a "change" and requests comments regarding "the potential impact of this change on the submission of ANDAs and 505(b)(2) applications." *Id.* at 65453. The proposal, however, would do no more than clarify FDA's current policy of listing patents claiming different crystalline forms of the active ingredient than found in the marketed product. *See e.g.*, FDA docket number 00P-0499. Prior to the Notice, FDA never indicated any disagreement with developing legal precedent on the issue.<sup>5</sup> Accordingly, the Agency's proposal does not represent a change in policy and thus will have no impact on ANDA and 505(b)(2) applicants.

FDA's response to the Apotex citizen petition belies any claim that FDA policy does not currently provide for the listing of such patents.<sup>6</sup> As explained above, in its citizen petition, Apotex sought to de-list two patents claiming anhydrate forms of paroxetine hydrochloride. Paxil, as marketed, contains paroxetine hydrochloride hemihydrate. Apotex sought approval of paroxetine hydrochloride asserted to be in the anhydrate form. Apotex then argued that because the two patents claimed a different form of paroxetine hydrochloride, albeit the one for which they sought approval, the patents did not "claim" the listed drug. FDA, however, found that listing of the two patents complied with the statute and applicable regulations.<sup>7</sup> To find otherwise, the FDA would have had to assert that the term "drug" should be interpreted differently in two sections of the Act.

FDA noted that for purposes of section 505(j), the Agency considers the anhydrate and hemihydrate forms of drug substances to be pharmaceutical equivalents and to

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<sup>5</sup> *See also Zenith Labs, Inc. v. Abbott Labs, Inc.*, 1996 WL 33344963 (D.N.J. Aug. 7, 1996); *Ben Venue Labs, Inc. v. Novartis Pharm. Corp.*, 10 F. Supp.2d 446 (D.N.J. 1998). Although the Agency states in the Notice that it "implicitly" did not accept the reasoning of these cases, the Agency cited these cases *with approval* in denying the Apotex petition.

<sup>6</sup> *See* Response from Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research, to Hugh L. Moore et al., Lord, Bissel & Brook, dated Nov. 21, 2000 (FDA docket number 00P-0499) (hereinafter "Response to Apotex Citizen Petition").

<sup>7</sup> Response to Apotex Citizen Petition at 5.

contain “the same active ingredient”. *See Id.* at 6 n.16. Specifically, the Agency explained, “Paroxetine hydrochloride anhydrate and paroxetine hydrochloride hemihydrate are pharmaceutical equivalents and contain the same active ingredient, paroxetine hydrochloride.” *Id.* FDA was thus faced with the issue of whether patents claiming the “the same active ingredient” as found in the marketed drug, but in a different form, claim the approved drug. In denying the Apotex petition, FDA essentially answered in the affirmative.<sup>8</sup>

FDA, although aware that the disputed patents in the Apotex situation claimed anhydrous paroxetine hydrochloride in the anhydrate form -- not the hemihydrate form found in Paxil -- at no time stated that patents are listable only if they claim the form of the drug actually present in the marketed drug product. If that were FDA’s policy at the time, it would have clarified the standard for patent listing or required additional certification from GSK in the same manner it did in the Pfizer and Biovail instances discussed in the Notice. In the former case, Pfizer submitted information on a patent claiming a tablet formulation of diltiazem. FDA refused to list the patent, however, without a certification that the tablet formulation was approved. In the Biovail case, the FDA stated that the Agency’s primary responsibility is “to clarify the identity of the approved drug product.”<sup>9</sup> There, Biovail had submitted a patent claiming a formulation of diltiazem hydrochloride containing both immediate release powder and time-release beads. FDA determined, however, that the only approved form of the drug contained only the time-release beads, and required Biovail to recertify to the patent at issue. In contrast, FDA did not require any sort of additional declaration from GSK either at the time of the original certification or pursuant to the Apotex Citizen Petition. While the Proposed Rule may have closed the loop by stating that different forms of the same active ingredient are listable as claiming the approved drug, a step it declined to take directly in its response to Apotex, this position was clearly presaged by the Agency’s prior actions.

That FDA’s proposal is not a change in policy is significant both for purposes of the Agency’s implementation regime and for NDA holders, such as GSK. FDA must clarify for the record that such patents have indeed been listable under past Agency practice and interpretation, consistent with applicable legal precedent.

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<sup>8</sup> *Id.* at 6, n. 18.

<sup>9</sup> *See* Letter from Ralph Lillie, Director, Office of Information Technology, Center for Drug Evaluation and Research, to Biovail Laboratories, Inc., dated March 23, 2001, at 4.

### **3. Listing Of Polymorphs Does Not Preclude Challenging ANDA Eligibility**

GSK generally agrees with FDA that it is logical to interpret the patent listing criteria and the ANDA approval provisions consistently and symmetrically. Both requirements turn on the definition of the term “drug”. For ANDA purposes, the applicant must establish that the “active ingredient of the [ANDA] drug is the same as that of the listed drug,” 21 U.S.C § 355(j)(2)(A)(ii)(1), and for listing purposes, the statute requires the submission of patent information for each patent that claims “the drug.” 21 U.S.C §355(b)(1). Thus if an ANDA “drug” is considered the same as the listed “drug,” even though a polymorphic form, then a patent claiming the ANDA “drug” must claim “the drug” and be listable. However, as noted by the Agency, there may be situations where polymorphic forms of a substance may differ materially in their clinical profile, 67 Fed. Reg. 65453, and, therefore, there may be instances in which a polymorphic form may not be ANDA-eligible. Because the question of “sameness” for alternative solid state forms may not be settled at the time patent listing is required, and indeed may be the subject of future administrative or legal proceedings, GSK believes that the new rule should not condition polymorph patent listing on a concession of ANDA eligibility. Rather, NDA sponsors should be free list a polymorph patent as long they have a good faith belief that FDA may be open to treating the polymorph claimed by the patent as the “same,” for purposes of Section 505(j), as the form of the drug substance in the marketed product. There should be no requirement that the patent holder concede that the polymorph is ANDA eligible when additional data might be necessary to establish the sameness of the new form.

### **4. Claim-by-Claim Listing**

GSK does not believe that the proposed requirement for listing individual claims is appropriate or consistent with the statute. Paragraph IV certifications reference the patent, not specific claims, and, indeed, it is irrelevant to the listing requirement whether some of the claims in the patent would not be listable. At most, a reasonable requirement would be to identify one claim that is listable, but there is no basis or reason to require a claim-by-claim listing. Further, whether or not a specific claim is identified as being listable, the rule should clarify that there is no estoppel to such claim being asserted as a condition of triggering the 30-month stay. Moreover, we do not understand the rules to limit what claims may be asserted in a Hatch-Waxman patent infringement action, which is beyond the province of the agency.

### **5. Product by Process Patents**

GSK agrees that product by process patents are listable. GSK agrees with the Agency that “product by process patents differ from process patents because, in a product by process patent, the patented invention is the product (as opposed to the process used in making the product).” 67 Fed. Reg. at 65452 (citing *In re Bridgeford*, 357 F.2d 679, 682 (CCPA 1966)). There is no basis in patent law for treating product by process patents as unlistable process patents. See also *Atlantic Thermoplastics Co. v. Faytex Corp.*, 970 F.2d 834, 845 (Fed. Cir.

1992) (“Though using only process terms, a product-by-process applicant [seeks] rights to a product, not a process.”).

In the Notice, the Agency invited comment “on ways to ensure that only appropriate product by process patents are listed, while maintaining the Act’s restriction against listing process patents.” 67 Fed. Reg. at 65452. GSK believes that the appropriate test for listing product by process patents is that set forth by the Agency for the listing of product patents: First, for product by process patents that claim a drug product, “the applicant shall submit information only on those patents that claim a drug product that is the subject of a pending or approved application.” *Id.* at 65464 (to be codified at 21 C.F.R. § 314.53(b)). Second, for product by process patents that claim a drug substance, “the applicant shall submit information only on those patents that claim the form of the drug substance that is the subject of the pending or approved application or that is the ‘same’ as the active ingredient that is the subject of the approved or pending application within the meaning of section 505(j)(2)(A)(ii) of the act.” *Id.* This approach recognizes that product by process patents are properly classified as product patents and subjected to the same analysis for purposes of determining their listability under the Act.

Treatment of product by process patents in this way is also supported by the Agency’s recognition that listing of drug substance patents should be consistent with the standards for submission of ANDAs under the act. GSK agrees with the Agency that

[i]f a generic drug product can be the “same” as the reference listed drug, notwithstanding differences in the drug substances’ physical form, then it is consistent to interpret “drug substance,” for purposes of listing patent information, as including drug substances having different physical forms.

67 Fed. Reg. at 65452. If an ANDA might be submitted for a generic drug product containing the drug substance as claimed in a product by process patent on the basis of an assertion by the applicant that the drug substance is the “same” as that in the approved product, then the product by process patent also claims the approved drug for purposes of patent listing. Inclusion of such patents provides notice to the ANDA applicant and the opportunity to deal with all the patent issues prior to approval -- thus serving the goals of Hatch-Waxman. Indeed, omission of such patents from the Orange Book would threaten the same “waste in agency and industry resources” presented by omission of other patents claiming drug substances. *See id.*

## **6. Patents Claiming Drug Delivery Systems**

GSK also requests that FDA clarify that patents covering devices or containers that are integral to a drug delivery system are properly listed in the Orange Book. GSK agrees with FDA that patents purely claiming drug packaging and/or containers do not “claim the drug” for listing purposes and are thus not listable. This listing prohibition, however, must not be read to preclude the listing of patents claiming devices or containers that are an integral part of a drug

delivery system, such as asthma inhalation devices, nasal inhalers, trans-dermal patches, and pre-filled syringes. Unlike drug containers and packaging, drug delivery aspects of integrated device/drug combination products are not “distinct from the approved product.” 67 Fed. Reg. at 65451. Rather, such delivery devices are critically related to the bioavailability and thus the safe and effective administration of the drug. In fact, a device “containing a drug substance as a component with the primary purpose of the combination product being to fulfill a drug purpose is a combination product and will be regulated as [a drug] by CDER.”<sup>10</sup> An example of such a product is GSK’s SEREVENT DISKUS®, which consists of a powder formulation of salmeterol xinafoate administered through a specially designed plastic inhalation delivery system called the DISKUS. The FDA-approved prescribing information states that the DISKUS “is the delivery component [] and is an integral part of the drug product.” Such delivery systems are parts of the “approved drug product” and thus patents so claiming should be properly listable.

#### **7. FDA Must Only Apply Its Rule Prospectively**

In the Notice, FDA proposes to apply any final rule it should adopt to patents filed for an NDA not approved prior to the effective date of the rule. 67 Fed. Reg. at 65457. If, however, an NDA is approved before the final rule becomes effective, “any patent listed before that date would be subject to the pre-existing regulation.” *Id.* ANDAs and 505(b)(2) applications submitted after the rule’s effective date, however, would be subject to FDA’s revised notice requirements. *Id.* ANDAs and 505(b)(2) applications submitted before the rule’s effective date would be subject to the current notice requirements and thus could be subject to multiple 30-month stays. *Id.* Patent information filed after the final rule’s effective date, however, would be “subject to the final rule’s patent listing and patent declaration requirements, and ANDA or 505(b)(2) application applicants would not have to provide notice if their application previously contained a paragraph IV certification.” *Id.*

GSK agrees that FDA must continue to apply its current regulations to pending NDAs and can only apply whatever rule it ultimately adopts prospectively. As FDA explained in the preamble to its proposed rules, if the Agency were to adopt an alternate implementation plan, it “would risk upsetting legitimate expectations held by those who had relied on our earlier interpretation of the act.” *Id.* Such an approach is consistent with the Agency’s implementation policy of the new definition of “court” (i.e., district court) for purposes of activating the “court decision” trigger of 180 day exclusivity. As the Agency explained in its March 2000 Guidance, “applicants who have made certain business decisions in good faith reliance upon an FDA

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<sup>10</sup> FDA, “Intercenter Agreement Between the Center for Drug Evaluation and Research and The Center for Devices and Radiological Health,” available at <<<http://www.fda.gov/oc/ombudsman/drug-dev.htm>>>

regulation should not be penalized for their actions.”<sup>11</sup> Similarly, here, a prospective implementation plan would “recognize[] the industry’s reliance on the previous definition”.<sup>12</sup>

Moreover applying the Proposed Rule to claims currently being litigated, for example to lift 30-month stays currently in place, would be impermissibly retroactive. A retroactive regulation “attaches new legal consequences to events completed before its enacted” or “takes away or impairs vested rights acquired under existing laws.”<sup>13</sup> As the D.C. Circuit recently explained, in determining whether a rule can be applied retroactively, “[t]he critical question is whether a challenged rule establishes an interpretation that ‘changes the legal landscape.’”<sup>14</sup> A new rule that is substantively inconsistent with previous regulations or Agency practice, as the notice requirements of the Proposed Rule would be, “is retroactive as applied to pending claims.”<sup>15</sup>

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GSK appreciates the opportunity to comment on this Proposed Rule.

Sincerely,



Donald F. Parman  
Vice President, Legal Operations

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<sup>11</sup> Guidance for Industry: Court Decisions, ANDA Approvals, and 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act (“March 2000 Guidance”).

<sup>12</sup> *Id.*; see *Mylan Pharm., Inc. v. Shalala*, 81 F. Supp. 2d 30, 45 (D.D.C. 2000) (indicating that it would be “inequitable to penalize” company that had endured lengthy litigation in reliance upon FDA regulation that had been upheld by circuit court).

<sup>13</sup> *Landgraf v. USI Film Prods.*, 511 U.S. 244, 269-70 (1994).

<sup>14</sup> *National Mining Assoc. v. Department of Labor*, 292 F.3d 849, 859 (D.C. Cir. 2002) (citations omitted).

<sup>15</sup> *Id.* at 860; see *Celtronix Telemetry v. FCC*, 272 F.3d 585, 588 (D.C. Cir. 2001) (citing *Bowen v. Georgetown University Hospital*, 488 U.S. 204, 219 (1988) (Scalia, J. concurring (Retroactive rule “alters past legal consequences of past actions”))).