GPhA
Generic Pharmaceutical Association

1620 I Street, NW • Suite 800 • Washington, DC 20006
202-833-9070 • Fax: 202-833-9612 • Email: info@gphaonline.org

December 10, 2001

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

Re: Docket No. 01P-0323/CP1
COMMENTS OF THE GENERIC PHARMACEUTICAL ASSOCIATION (GP*h*A)

Dear Madam or Sir:

These comments of the Generic Pharmaceutical Association (GP*h*A) are respectfully submitted in response to the July 27, 2001 Citizen Petition filed on behalf of Pfizer Inc., and Pharmacia Corporation (Petitioners), in which Petitioners request that FDA roll back 17 years of consistent regulatory policy regarding so-called "505(b)(2) NDAs" and adopt instead a highly restrictive, anti-competitive policy that is contrary to the plain language of the Federal Food, Drug, and Cosmetic Act. As shown below, there is absolutely no basis for FDA to adopt the radical interpretations advocated by Petitioners, and there would be no basis for the courts to endorse Petitioners' approach in the event Petitioners (or anyone else) were to bring a judicial challenge to FDA's interpretation and implementation of 21 U.S.C. § 355(b)(2). In addition, section 505(b)(2) as implemented by FDA strongly encourages further innovative product development that otherwise would not occur, thus improving and expanding the healthcare choices of all Americans while simultaneously promoting price-lowering competition in the hyper-inflated market for prescription therapeutic products. Accordingly, the Petition should be denied.

THE PLAIN LANGUAGE OF THE STATUTE SUPPORTS FDA'S REGULATION AND REQUIRES THAT THE PETITION BE DENIED

The Petitioners' request that FDA abandon its long-held interpretation of section 505(b)(2) finds no support in the statutory language, and in fact, section 505(b)(2), on its face, clearly and unambiguously permits approval of:

> An application . . .for which the investigations . . . relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. . . .

21 U.S.C. § 355(b)(2). *Accord* 21 U.S.C. §§ 355(c)(3)(D)(i), (ii), (iii), (iv), and (v) (reiterating that 505(b)(2) NDAs may be approved based upon investigations for which the applicant has no right of reference). Thus, as discussed *infra*, Petitioners' argument that section 505(b)(2) merely codified FDA's former "Paper NDA Policy" is simply incorrect.

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Where, as here, the language of a statute is clear, FDA and the courts must give effect to the statute as written. *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 81 L. Ed. 2d 694, 104 S. Ct. 2778 (1984). Petitioners' argument that the statute "does not state or even suggest that approvals based on prior findings of safety and effectiveness of an innovator's product are permitted under section 505(b)(2)," is thus incorrect.

FDA'S REGULATIONS REASONABLY IMPLEMENT THE PLAIN LANGUAGE AND CONGRESSIONAL INTENT OF SECTION 505(b)(2) AND THEREFORE WILL WARRANT DEFERENCE FROM THE COURTS

Even if the statute was not clear and unambiguous, FDA's regulatory implementation of section 505(b)(2) is reasonable and permissible, and therefore should not be altered as requested by Petitioners. An agency's interpretation of its organic statute is entitled to substantial deference from the courts, Chevron 467 U.S. at 844, and "an agency's construction of its own regulations is entitled to an exceedingly deferential standard of review such that the court is not to decide which among several competing interpretations best serves the regulatory purpose." Trinity Broadcasting of Florida, Inc. v. FCC, 211 F.3d 618, 625 (D.C.. Cir. 2000). Accord, Thomas Jefferson Hospital v. Shalala, 512 U.S. 504, 512 (1994); Wyoming Outdoor Council v. United States Forest Service, 165 F.3d 43, 52 (D.C. Cir. 1999). And, where as here, the agency's interpretation is longstanding and heretofore unchallenged, judicial deference is heightened even further. See Motor Vehicle Mfrs. Ass'n. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 42-43 (1983).

FDA's 505(b)(2) regulations provide that:

> Any person seeking approval of a drug product that represents a modification of a listed drug (e.g., a new indication or new dosage form) and for which investigations, other than bioequivalence or bioavailability studies, are essential to the approval of the changes may. . . submit a 505(b)(2) application. This application need contain only that information needed to support the modification(s) of the listed drug.

21 C.F.R. § 314.54(a). As FDA explained this regulation,

> FDA believes that a more consistent, less burdensome interpretation of the 1984 Amendments is to allow a generic applicant to submit a 505(b) application for a change in an already approved drug that requires the submission and review of investigations . . . . Therefore, under proposed § 314.54, applications will be accepted for changes requiring the review of investigations, including changes in dosage form, strength, route of administration, and active ingredients (in a combination product), as well as new indications.

54 Fed. Reg. at 28892 (July 10,1989).

Because FDA's regulations, 21 C.F.R. § 314.54, and its October 1999 Draft Guidance (which explained and reiterated the policy established by section 314.54), are consistent with, and

reasonably and permissibly interpret the plain language and Congressional intent of section 505(b)(2) to allow approval of NDAs based on FDA's prior findings of safety and efficacy, Petitioners' request that FDA revoke this regulation must be denied.

COMPARISONS BETWEEN THE ANDA PROCESS AND THE 505(b)(2) PROCESS SUPPORT FDA'S INTERPRETATION OF SECTION 505(B)(2)

Petitioners have spun a convoluted and baseless theory seeking to argue that the narrowly structured approval requirements for ANDAs under section 505(j) preclude the separate, broader, but unambiguous approval pathway provided by section 505(b)(2). Specifically, Petitioners make the self-contradictory argument that if Congress had actually intended FDA to implement section 505(b)(2) as written, Congress would have made section 505(b)(2) identical to section 505(j):

> If Congress had intended for the Agency to approve applications under section 505(b)(2) that rely on an innovator's proprietary data to establish safety and efficacy, it would have included the same express language in section 505(b)(2) that is included in section 505(j).

Pet. at 4. This argument is, of course, absurd because section 505(b)(2) specifically and unambiguously authorizes FDA to approve "An application submitted under paragraph (1) for a drug for which the investigations described in clause (A) of such paragraph and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted..."

Petitioners' argument is also flawed because it fails to recognize that – despite the different requirements for approval of ANDAs and 505(b)(2) NDAs – there is no regulatory element of an ANDA that is prohibited from being met by a 505(b)(2) NDA. More specifically, the basic mandatory requirements for ANDAs – "sameness" to the innovator drug, and bioequivalence, 21 U.S.C. § 355(j)(2)(A)(i)-(v) – are deemed necessary to allow simplified FDA review and approval of generic drugs, and FDA is forbidden from requiring any clinical data other than bioequivalence data for ANDA products. 21 U.S.C. § 355(j)(2)(A). In contrast, 505(b)(2) drugs are not required to be the same in all respects as an innovator product, but they are not prohibited, as an absolute matter, from being the same in any or most relevant respects. Thus, section 505(b)(2) products will usually differ from the innovator product in some way that requires limited additional clinical or pre-clinical data (which cannot be required of an ANDA applicant). For example, a generic recombinant drug product may be the same as the innovator version in all respects except the source cell line, but proof of such sameness may require some additional clinical data. Because the necessity for additional clinical data would preclude an ANDA, Congress permitted sponsors of such products to obtain approval under section 505(b)(2) by relying on previous safety and efficacy determinations along with additional data necessary to support the safety and efficacy of the difference(s).

Moreover, Petitioners' focus on the differences between the 505(j) and 505(b)(2) approval mechanisms ignores the fact that both ANDAs and 505(b)(2) NDAs share important similarities which further support FDA's 505(b)(2) policy. For example, applicants under both provisions must certify to relevant patents and provide a "Paragraph IV Notification" if any patents are challenged as being invalid or not infringed by the competing drug. Innovators may sue a paragraph iv 505(b)(2)

applicant or a Paragraph IV ANDA applicant and obtain a 30-month approval stay. See 21 U.S.C. § 355(b)(2)(A), (b)(3), and (c)(3)(C); 21 U.S.C. §§ 355(j)(2)(A)(vii), (j)(2)(B), and (j)(5)(B)(iii). The purpose of the Paragraph IV Certification requirement is to give innovators a procedural mechanism to help protect intellectual property rights that might be impacted by approval of a competing product. The Paragraph IV certification and litigation requirements are significant burdens for ANDA and 505(b)(2) applicants that did not exist before 1984. These requirements were intended to provide a counter balance to these new streamlined approval requirements established by Hatch-Waxman, and it makes no sense to argue, as Petitioners do, that Congress would have added these restrictions to section 505(b)(2) if that provision did not also provide a new more expedited approval mechanism for competing versions of approved drugs. In other words, the similar addition of the patent certification process to both section 505(j) and 505(b)(2) strongly supports FDA's position that applicants under both sections may rely in a similar manner on the Agency's prior findings of safety and efficacy of innovator products.

SECTION 505(b)(2) DID NOT CODIFY FDA'S FORMER "PAPER NDA" POLICY

Petitioners argue that "the legislative history demonstrates that Congress....added section 505(b)(2) to the FFDCA to codify FDA's 'paper NDA' policy, as defined by the Finkle Memorandum, which does not permit FDA to rely upon innovator data." Pet. at 10. This contention is insupportable.

The "Paper NDA Policy" was published in the Federal Register in 1981. 46 Fed. Reg. 27396 (May 19, 1981). Petitioners argue that 505(b)(2) must be read to have the same meaning as the Paper NDA Policy – i.e., to bar approval of 505(b)(2) NDAs that rely on another company's investigations. Pet. at 10-14. However, the Paper NDA Policy is very different from section 505(b)(2) and the differences show that Congress did not intend to codify the Paper NDA Policy.

The Paper NDA Policy stated that "Present interpretation of the law is that no data in an NDA can be utilized to support another NDA without express permission of the original NDA holder." 46 Fed. Reg. 27396 (May 19, 1981) (emphasis added). In contrast, section 505(b)(2) allows approval of "An application. . .for a drug for which the investigations. . .relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. . . . 21 U.S.C. § 355(b)(2). Thus, section 505(b)(2) constituted a clear change from the old Paper NDA Policy.

Contrary to Petitioners' argument that "the term 'paper NDA' is liberally cited throughout the legislative history of section 505(b)(2), providing significant evidence that Congress intended to codify the Agency's prior paper NDA policy in section 505(b)(2)," Pet. at 11, the legislative history actually shows that Congress intentionally departed from, and significantly broadened, the Paper NDA Policy in creating 505(b)(2) because it considered the old Paper NDA Policy to be inadequate:

> Some have suggested that "Paper NDAs" be used to approve generic equivalents of pioneer drugs approved after 1962. Under the Paper NDA procedure, the generic manufacturer may submit scientific reports, instead of clinical trials, to support findings of safety and efficacy. This procedure is inadequate, however, because FDA

> estimates that satisfactory reports are not available for 85 percent of all post-1962 drugs.

H. Rep. Rpt. 98-857, Part 1 at 16 (June 21, 1984) (emphasis added). The Petition thus makes the ludicrous argument that Congress intended to codify a policy that it expressly stated was flawed.

Moreover, the fact that the term "Paper NDA" is "liberally cited" in the legislative history does not support the conclusion that 505(b)(2) is nothing more than a codification of the Paper NDA Policy. The House Report specifically provided a new definition of the term "Paper NDA" as follows:

> *Paper NDA's*
> Paper NDA's are defined as any application submitted under section 505(b) of the FFDCA in which the investigations relied upon by the applicant to show safety and effectiveness were not conducted by or for the applicant and the applicant has not obtained a right of reference or use from the person who conducted the studies or from whom the studies were conducted.

H. Rep. Rpt. 98-857, Part 1 at 32 (June 21, 1984). *See also* H. Rep. Rept. 98-857 Part 2 at 19 (August 1, 1984) (using same new definition). The new definition of "Paper NDA" is consistent with section 505(b)(2) and is inconsistent with the old Paper NDA Policy, and with good reason: Congress rejected the old Paper NDA Policy as "inadequate."

FDA has long and appropriately recognized the Congressional change from the Paper NDA Policy to the 505(b)(2) approach: "[a]lthough similar to FDA's 'paper NDA' policy, section 505(b)(2) of the act has broader applicability. *** Thus, section 505(b)(2) of the act covers not only literature-supported NDA's for duplicates of approved drugs, but any NDA's for drug products that rely for approval on studies not conducted by or for the applicant or for which the applicant does not have a right of reference." 54 Fed. Reg. 28872, 28875 (July 10, 1989) (proposed regulations implementing Hatch-Waxman). No company challenged or objected to this interpretation, see 57 Fed. Reg. at 17954-55, and FDA therefore adopted 21 C.F.R. § 314.54 as proposed, with only one unrelated change. *Id.*

Finally, Burroughs Wellcome Co. v. Owen, 630 F. Supp. 787 (E.D.N.C. 1986), cited by Petitioners at page 11, note 29, does not support Petitioners' arguments because that case was a preliminary decision involving a pre-Hatch-Waxman application, and the decision did not turn on the definition of "Paper NDA," but rather on the fact that Burroughs had not shown a "likelihood of success" necessary for its requested Temporary Restraining Order. *Id.* at 790-791.

LATER STATUTES DO NOT UNDERMINE FDA's INTERPRETATION OF 505(b)(2)

Petitioners argue that the Generic Drug Enforcement Act (GDEA) and the Food and Drug Modernization Act (FDAMA) "ratified [Congress'] historical position that section 505(b)(2) applications are simply a type of full NDA, and that FDA, therefore cannot approve these applications in reliance on an innovator's proprietary data and FDA's prior findings of safety and effectiveness." Pet. at 15-16. Petitioners are wrong.

GDEA was a response to the generic drug scandal involving submission of fraudulent bioequivalence data in ANDAs (under section 505(j)). Bioequivalence data is not *required* in 505(b)(2) NDAs (although it is often submitted where appropriate). The fact that GDEA did not directly relate to 505(b)(2) NDAs thus has nothing to do with whether safety and efficacy can be demonstrated by reliance on prior investigations, as expressly permitted by the statute.

An Act of Congress that does not specifically address, and is not inconsistent with, an existing statutory provision cannot operate to repeal the existing provisions. There is no suggestion that in GDEA Congress intended to secretly repeal the plain language of 505(b)(2, or to "ratify" a "historical position" (the former Paper NDA Policy) that Congress *expressly* rejected as "inadequate."

GDEA protects against fraud committed in connection with any drug application, *see* 21 U.S.C. § 335a(a)(2), so the fact that it did not specifically address 505(b)(2) NDAs in the same way it addressed ANDAs in no way makes 505(b)(2) NDAs more prone to potential fraudulent activities.

Section 118 of FDAMA required FDA to develop guidances relating to NDAs and Biologics License Applications ("BLAs"). Petitioners admit that this section did not change any substantive provisions of section 505(b), and this provision therefore cannot operate to repeal the plain language of 505(b)(2).

Both GDEA and FDAMA were passed after FDA's final 505(b)(2) regulations. Congress is presumed to have full knowledge of existing law and the agency's regulations, and later statutes cannot repeal existing laws and regulations unless Congress does so explicitly. Pfizer v. Shalala, 753 F.Supp. 171, 178 (D. Md. 1990) ("Congress is assumed to know the judicial or administrative gloss given to particular statutory language, and therefore is assumed to have adopted the existing interpretation unless it affirmatively indicates otherwise."). Here, even Petitioners admit that GDEA and FDAMA do not "affirmatively" reject FDA's interpretation of 505(b)(2), so Petitioners' arguments are without merit.

APPROVAL OF A 505(b)(2) NDA WOULD NOT BE AN UNCONSTITUTIONAL "TAKING" AND WOULD NOT VIOLATE THE INNOVATOR'S TRADE SECRET RIGHTS

Under Ruckelshaus v. Monsanto, 467 U.S. 986 (1984), FDA approval of 505(b)(2) NDAs would not constitute an unconstitutional "taking" because it would not interfere with a "reasonable investment-backed expectation" of the innovator company. In Monsanto, the Court found that Monsanto was on notice after the 1978 FIFRA amendments that EPA would use proprietary data submitted by an original pesticide applicant in approving subsequent applications "without [the original applicant's] permission." Id. at 1006. Thus, the Court held, Monsanto had no reasonable expectation that "EPA would keep the data confidential beyond the limits prescribed in the amended statute itself." Id. Likewise, the 1984 Hatch-Waxman amendments put innovator drug companies on notice that FDA could rely on the Agency's safety and efficacy determinations in support of subsequent 505(b)(2) NDAs without the pioneer's permission.

As discussed above, the plain language of section 505(b)(2), and FDA's longstanding regulations unequivocally allow subsequent applicants, and FDA, to rely on investigations for which the 505(b)(2) applicant has no right of reference. As the Monsanto Court concluded, "a voluntary

submission of data by an applicant in exchange for the economic advantages of a registration can hardly be called a taking." Monsanto, 467 U.S. at 1007.

Neither the Trade Secrets Act, FDA's Freedom of Information Act (FOIA) regulations, nor the court decisions cited by Petitioners prevent FDA approval of 505(b)(2) NDAs as contemplated by the statute and FDA's regulations. The Trade Secrets Act only prohibits the government from "publish[ing], divulg[ing], disclos[ing], or mak[ing,] known," trade secrets and does not bar internal agency reliance on its own safety and effectiveness conclusions about a previously studied drug. See Monsanto, 467 U.S. at 1009 (1984).

Similarly, 21 U.S.C. § 331(j) does not prohibit approval of 505(b)(2) NDAs as enunciated in the statute and FDA regulations. That section simply prohibits FDA employees from using certain trade secret information to the employee's "own advantage," or "revealing" such information to others outside of government. Moreover, the type of information protected is limited to "any method or process." The FDA's own conclusions about a drug's safety and efficacy thus are outside the scope of this protection even if such information was "revealed" or used to an employee's "own advantage." FDA's implementing regulations are consistent with this interpretation. See 21 C.F.R. § 20.61(a). See also Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C. Cir. 1983); Tri-Bio Laboratories, Inc. v. United States, 836 F.2d 135, 140, and 141 n. 7 (3rd Cir. 1987) ("in the absence of any 'provision of law' proscribing internal agency use, the pioneer could not have had a reasonable expectation that the agency would not consult the submitted data to evaluate applications submitted by other manufacturers"), cert. denied, 488 U.S. 818 (1988). Likewise, the Freedom of Information Act is no barrier to FDA approval of 505(b)(2) NDAs. See 5 U.S.C. § 552(a), (b)(4); Tri-Bio Laboratories, 836 F.2d at 141 n.7. See also, FDA's FOIA regulations, 21 C.F.R. Part 20; § 314.430 (human drugs); § 601.51 (biologics); §814.9 (devices); and § 514.11 (animal drugs).

Moreover, there are at least two explicit "provisions of law" allowing FDA reliance on external information to approve 505(b)(2) NDAs – section 505(b)(2) itself, and section 505(l) (21 U.S.C. § 355(l)). Section 505(l) requires that safety and effectiveness data filed in support of an NDA must be made publicly available as of the date the first ANDA for the drug "could be made effective if such an application had been submitted." 21 U.S.C. § 355(l). The earliest ANDA approval date coincides with the earliest 505(b)(2) approval date because both types of applications are dependent on the resolution of the same type of patent challenges – i.e., whether the patent is invalid, unenforceable, or would not be infringed by the proposed ANDA or 505(b)(2) product, as described in 21 U.S.C. § 355(j)(5)(B) and 21 U.S.C. § 355(c)(3). Thus, because FDA's approval of a 505(b)(2) NDA cannot violate any reasonable investment-backed expectation of the innovator company, there can be no unconstitutional taking.

505(b)(2) DRUGS MAY RECEIVE "AB" ORANGE BOOK RATINGS

The criteria by which FDA may assign therapeutic equivalence ratings are scientific, and are not based on statutory semantics or the regulatory pathway by which a drug was approved. As described in the Orange Book:

> FDA classifies as therapeutically equivalent those products that meet the following general criteria: (1) they are approved as safe and effective; (2) they are pharmaceutical equivalents in that they (a) contain identical amounts of

> the same active drug ingredient in the same dosage form and route of administration, and (b) meet compendial or other applicable standards of strength, quality, purity, and identity; (3) they are bioequivalent in that (a) they do not present a known or potential bioequivalence problem, and they meet an acceptable *in vitro* standard, or (b) if they do present such a known or potential problem, they are shown to meet an appropriate bioequivalence standard; (4) they are adequately labeled; and (5) they are manufactured in compliance with Current Good Manufacturing Practice regulations.

Orange Book, Preface. See also, 21 C.F.R. § 320.1 (defining "bioavailability," "pharmaceutical equivalents," and "bioequivalence"). The fact that the Orange Book refers to the bioequivalence definition set forth in the ANDA provisions of the Act, 21 U.S.C. § 355(j)(8)(B), see Pet. at 27, does not mean that drugs approved under 505(b)(2) cannot also meet the technical criteria for an AB rating. Indeed, the Orange Book itself notes that section 505(j)(8)(B) merely "describes one set of conditions under which a test and reference listed drug shall be considered bioequivalent," and FDA has in the past given "A" therapeutic equivalence ratings to 505(b)(2)-approved drugs.

Because therapeutic equivalence ratings are completely independent of the regulatory approval pathway by which a drug reaches the market, if a sponsor of a product approved under section 505(b)(2) can show that the product meets the therapeutic equivalence criteria, FDA may, and must, grant that product an "AB" rating.

THE PETITION COULD UNNECESSARILY FORCE FDA TO WITHDRAW APPROVAL OF NUMEROUS DRUGS PREVIOUSLY APPROVED UNDER SECTION 505(b)(2)

The 505(b)(2) approval pathway has been used extensively over the years, and many generic and well known brand name drugs are currently marketed based on approvals under section 505(b)(2) without any safety or efficacy problems related to the 505(b)(2) approval pathway. In fact, section 505(b)(2) is often used to approve labeling changes to add new warnings, precautions, or contraindications that are necessary for the safe use of the drug. For example, new geriatric labeling precautions for Verelan, Inderal, and Sectral were approved under section 505(b)(2). In short, experience has shown that the 505(b)(2) process works and it works well. The following is a partial list of drugs for which approval was granted in whole or in part under section 505(b)(2):

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- Avita (tretinoin)
- Betapace (sotalol)
- Canasa (mesalamine suppositories)
- Cernevit-12 (multivitamins for infusion)
- Clindamycin gel, 1%
- Clinimix (amino acids in dextrose)
- Dextrose 50%
- Dimetane
- EpiPen autoinjectors
- Fortovase
- GlucaGen (glucagon rDNA)
- Glucovance (glyburide and metformin HCl)
- Inderal (propanolol HCl)
- Invirase
- Levoxyl (levothyroxine sodium)
- Luxiq (betamethasone valerate)
- Multi-12
- Olux (clobetasol propionate)
- Preven
- Primsol
- Provera
- Repronex
- Roxicodone
- Sectral (acebutolol)
- Sulfamethoxazole/ trimethoprim/ phenazopyridine
- Tavist Allergy/Sinus/Headache
- Thalomid
- Tri-Nasal (triamcinolone acetonide)
- Travosol
- Unithroid (levothyroxine sodium)
- Verelan (verapamil HCl)
- Versed
- Videx
- Visicol
- Xopenex (levalbuterol HCl)
- 10% calcium chloride injection
- 20% ProSol (amino acids)

Not only have Petitioners failed to address this prior extensive use of 505(b)(2), they fail to mention that by granting the Petition, many marketed drugs could be forced off the market as having been unlawfully approved. Such a result not only would be a massive and expensive administrative nightmare for FDA, and potentially devastating to the affected companies, it would also be extremely detrimental to American patients who rely on the continued availability of these medicines. Given these facts, it would be contrary to the public interest to grant the Petition.

CONCLUSION

The Petition raises no credible basis upon which FDA could grant the radical relief requested by Petitioners, and the Petition should therefore be denied.

Respectfully submitted,

Steve Bende, Ph.D.
Vice President
Science, Professional and Regulatory Affairs

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