Greenberg Traurig

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

RE: Citizen Petition to Switch Allegra and Zyrtec from Prescription Drugs to Over the Counter.

Dear Sir or Madam:

Pursuant to 21 C.F.R. § 10.30, please find enclosed our citizen petition ("Petition") to switch Allegra (Fexofendaine Hydrochloride), Allegra D 12 Hour and 24 Hour (Fexofendaine Hydrochloride; Pseudophedrine Hydrochloride), and Zyrtec (Cetirizine Hydrochloride) and Zyrtec D (Cetirizine Hydrochloride; Pseudophedrine Hydrochloride) from prescription drugs to over-the-counter ("OTC").[1] The OTC switch sought by this Petition ought to granted for three reasons. First, the data from the prior Petition process demonstrated that OTC distribution of these drugs is consistent with FDA policy. Second, two FDA Advisory Committees meeting jointly recommended, based on the aforementioned data, that these drugs be sold over-the-counter. And finally, data from the OTC distribution of Claritin, a drug closely related to the ones that are subject to this Petition, confirms the findings of the agency and the advisory committees that OTC distribution is consistent with FDA policy and public safety.

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1 Allegra is distributed pursuant to three NDAs depending on the route of delivery: capsule (NDA #020625); tablet (NDA #020872); and suspension (NDA #021963). The enclosed Petition seeks to switch all three variants to OTC. Allegra-D 12 Hour is distributed pursuant to NDA #020786, and Allegra-D 24 Hour is distributed pursuant to NDA #021704. The term "Allegra" as used in this Petition includes the drugs distributed pursuant to the five aforementioned NDAs or any ANDAs refencing those NDAs.

Zyrtec is also distributed pursuant to three NDAs depending on the route of delivery: chewable tabel (NDA #021621); tablet (NDA #019835); and syrup (NDA #020346). The enclosed Petition seeks to switch these three variants of Zyrtec. Zyrtec-D is distributed pursuant to NDA #021150. The term "Zyrtec" as used in this Petition includes the drugs distributed pursuant to the four aforementioned NDAs or any ANDAs referencing those NDAs.

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The Petition is consistent with FDA policy to switch pharmaceuticals to OTC when:

- the benefits of over-the-counter availability outweigh the risks
- the potential for misuse and abuse is low
- the consumer can use the drugs for self-diagnosed conditions
- the drugs can be adequately labeled
- health practitioners are not needed for the safe and effective use of the product

These products have been sold OTC worldwide for many years, with an excellent safety record. [See-cite to data]. Claritin, a member of the same class of antihistamines as Allegra and Zyrtec, was approved by the FDA to be sold OTC in November, 2002, with extremely positive results. [See-cite to data]. The FDA Commissioner announced Claritin's switch with a press release (PO2-51), stating in part: "By making it easier to get this widely-used drug, today's action will enable many people to get less-sedating, effective relief for their allergy symptoms more quickly and at a lower cost. This approval reflects the FDA's commitment to bringing prescription drugs to the over-the-counter market when they can be used safely without a prescription." The safety records of Allegra and Zyrtec present a similarly compelling case to switch to OTC.

Our Petition is a reiteration of the prior citizen petition to switch second generation antihistamines from prescription to OTC. *See* Petition 98P-0610/CP1 (submitted by Blue Cross of California requesting that fexofendadine hydrochloride, loratadine and cetirizine hydrochloride be switch to OTC status). The prior petition was reviewed jointly by the Nonprescription Drugs Advisory Committee and the Pulmonary- Allergy Drugs Advisory Committee. The Committees having holding a hearing on May 11, 2001, and evaluating significant data that had bee submitted to them on both sides of the question, which recommended that Allegra, Zyrtec and Claritin be switched from prescription drugs to OTC. The FDA took no formal action on the broad committee recommendation, and, consequently five years later, we petition the FDA to switch all these drugs. In the intervening years, the positive OTC experience of Claritin has made case to switch these drugs even more compelling.

Based on the information provided in our petition, the non-sedating antihistamines Allegra and Zyrtec meet FDA criteria for an Rx to OTC switch. Consequently, we are requesting that you expedite the conversion of Allegra/ Allegra D and Zyrtec to OTC status.

Very truly yours,

Joel Stocker

Joel Stocker

Citizen Petition
to
The Commissioner of Food and Drugs
to
Switch Allegra and Zyrtec to OTC

March 12, 2007

Citizen Petition to Switch Allegra and Zyrtec to OTC

The undersigned submits this petition pursuant to Section 503(b)(3)[1] of the Food, Drug and Cosmetic Act ("FD&CA"), as amended, or any other statutory provision for which authority has been delegated to the Commissioner of Food and Drugs under 21 C.F.R. 5.10 to request the Commissioner of Food and Drugs to switch the following non-sedating antihistamine medications from prescription ("Rx") to over-the-counter ("OTC"):

Allegra (60 mg fexofenadine);
Allegra D (60 mg fexofenadine, 120 mg psudoephedrine);
Zyrtec (5 mg cetirizine and 10 mg cetirizine).

Statement of Grounds.

A. Factual Grounds.

Under the FD&CA, a drug is presumed available OTC unless it has toxic effects, requires a doctor's supervision or there is some other compelling reason to protect the public health. Allegra and Zyrtec, like Claritin (another non-sedating antihistamine) qualify for, and should be made available OTC.

Allegra and Zyrtec were the subject of a prior citizen petition by Blue Cross of California (now Wellpoint Health Networks) to switch them from Rx to OTC status. Consequently, we believe it to be helpful to include the following summary of activities associated with non-sedating (second generation) antihistamine medications:

1. FDA approves Zyrtec as a prescription drug for the treatment of allergic rhinitis in December, 1995.
2. FDA approves Allegra as a prescription drug for the treatment of allergic rhinitis in July, 1996.
3. Blue Cross of California petitions FDA in July, 1998 to exempt Allegra, Claritin and Zyrtec from prescription requirements for the reason that prescription requirements are unnecessary.
4. FDA, Nonprescription Drugs Advisory Committee & Pulmonary - Allergy Drugs Advisory Committee holds a hearing in May, 2001 on the OTC marketing of antihistamines and the safety profile of Claritin, Allegra and Zyrtec. The petitioner and others speak in favor of the petition and the manufacturers of the pharmaceuticals and others speak against it. The committee finds that loratadine (Claritin), fexofenadine (Allegra) and cetirizine (Zyrtec) have safety profiles acceptable for OTC

[1] Section 503(b)(3) provides in part: The Secretary may by regulation remove drugs subject to section 505 [NDA, ANDA] from the requirements of paragraph (1) [requiring a prescription] of this subsection when such requirements are not necessary for the protection of the public health.

marketing. The members of the committee voting for the switch make certain recommendations regarding labeling.[2]

5. Blue Cross of California subsequently withdraws its petition and, consequently, FDA takes no action on the matter.
6. After contending that OTC Claritin posed a risk to the public health before the advisory committee, Schering-Plough, the drug's maker, files a supplemental NDA to switch Claritin to OTC in March, 2002. Schering-Plough indicates in its petition that the drug is safe to use OTC when taken as directed by the label.
7. FDA approves switch of Claritin to OTC in November, 2002 for allergic rhinitis, and subsequently approves the drug for the OTC treatment of chronic idiopathic urticaria. In the FDA press release approving the switch Mark B. McClellan, M.D., Ph.D., the FDA Commissioner comments: "By making it easier to get this widely-used drug, today's action will enable many people to get less-sedating, effective relief for their allergy symptoms more quickly and at a lower cost. This approval reflects the FDA's commitment to bringing prescription drugs to the over-the-counter market when they can be used safely without a prescription."[3]
8. Following its launch in December 2002, Claritin became the number one OTC antihistamine brand (in total sales dollars). Claritin is consistently among the top three of hundreds of OTC drugs sold in the United States.[4]
9. Other pharmaceutical companies subsequently receive FDA approval for generic loratadine[5].

To qualify a prescription drug product for reclassification to OTC status, the drug must meet certain criteria for eligibility: First, the drug should have favorable adverse-event and drug-interaction profiles, relatively low toxicity and a low potential for abuse. Second, it should be marketed for a material time (a minimum of five years). Third, it should be marketed to a "material extent."[6] For the reasons set forth below, Allegra and Zyrtec meet these criteria for OTC eligibility for the treatment of for allergic rhinitis.

Allegra and Zyrtec have favorable adverse-event and drug-indication profiles, low toxicity and a low potential for abuse. Additionally, they are substantially safer than first generation antihistamines currently approved for sale OTC[7].

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[2] Nonprescription Drugs Advisory Committee & Pulmonary – Allergy Drugs Advisory Committee, Food and Drug Administration, Center for Drug Evaluation and Research, Petition 98P-0610/CP1, Final Minutes- May 11,2001.

[3] FDA Approves OTC Claritin, FDA News, PO2-51, November 27,2002.

[4] Schering-Plough News Release, Claritin OTC Brand Sales Surpass $1 Billion Mark in U.S., The Success of Claritin Confirms Schering-Plough's Expertise in Prescription-to-OTC Switches, March 22, 2005.

[5] According to FDA data (updated August 30,2005), Apotex, Morton Grove, Perrigo, Ranbaxy, Taro, Teva, Andrx, Impax Labs, Wyeth, Genpharm, Ranbaxy, Sandoz produce OTC loratadine.

[6] See, FDA, DIA Meeting, June 28,2005, p 15.

[7] See, Nonprescription Drugs Advisory Committee & Pulmonary – Allergy Drugs Advisory Committee, Food and Drug Administration, Center for Drug Evaluation and Research, Petition 98P-0610/CP1, Transcript- May 11,2001, comments by Jack Kern, Pharm.D., comparative incidence of sedation of first and second generation antihistamines, p27.

These pharmaceuticals have been marketed extensively in the United States for over five years and are widely considered to be safe and effective. In 2000, 15 million prescriptions (US) were written for Allegra and 13 million prescriptions (US) for Zyrtec[8]. US experience together with OTC experience in other countries demonstrates prior marketing to a material extent.

Maintaining Allegra and Zyrtec as prescription drugs, while more dangerous antihistamine and antihistamine/decongestant alternatives are available without a prescription, deprives patients of an additional choice of non-sedating antihistamines. This lack of choice results in a greater incidence of side effects associated with first generation OTC antihistamine alternatives, including safety concerns related to driving and operating machinery. Additionally, this unnecessary Rx requirement adds unnecessary costs to the health care system.

Allegra, Zyrtec and Claritin were the subject of the prior citizen's petition of Blue Cross of California to switch them to OTC status.[9] The petitioner submitted compelling evidence comparing the safety and efficacy of first generation antihistamines (which are sold OTC) with that of Allegra, Claritin and Zyrtec, as well as a meta-analysis of these drugs. Additionally, data were submitted regarding Canada's experience with the OTC sale of these drugs. We are incorporating by reference the data submitted by Blue Cross of California in support of its petition.[10] The petition received the overwhelming support of the FDA, Nonprescription Drugs Advisory Committee & Pulmonary - Allergy Drugs Advisory Committee. The favorable OTC experience of Claritin further validates the data submitted in the prior petition.

Lastly, Allegra and Zyrtec meet the regulatory requirements for non-prescription marketing[11]. The drugs' toxicity profiles, their methods of use, necessary collateral measures, safety and acceptability for self medication, safety profiles, low potential for misuse and therapeutic index of safety are materially the same as Claritin.

We enclose for your consideration an example label used for OTC loratadine (See, Exhibit "A") which we believe to be appropriate for other non-sedating antihistamines as well.

[8] Scott-Levin Source Prescription Audit.
[9] See. FDA, Petition 98P-0610/CP1.
[10] See, FDA Docket 98P-0610, Convert Allegra, Allegra-D, Claritin, Claritin-D, Zyrtec to OTC, CP 1, Sup 1, Sup 2.
[11] See, FDA, DIA Meeting, June 28,2005, pp 20-21.

In summary, Allegra and Zyrtec's existing safety, marketing and regulatory record provides a compelling case for their OTC switch:

- Blue Cross of California presented evidence of their safety and suitability for OTC.
- The FDA Nonprescription Drugs Advisory Committee & Pulmonary – Allergy Drugs Advisory Committee recommended their switch in 2001.
- Claritin has a successful record as an OTC drug, validating prior data and the conclusion of the advisory committee.
- Allegra and Zyrtec have for many years been successfully marketed OTC in other countries.

B. Legal Grounds.

The FDA has the clear authority to approve a prescription to OTC switch based on a citizen's petition, and without sponsor consent. For your consideration, we have attached as Exhibit "B" a memorandum of law addressing this issue.

Environmental Impact.

Petitioner claims categorical exclusion under Section 25.30(h) and 25.30(k).

Certification.

The undersigned certifies that, to the best of his knowledge and belief, this petition includes all information and views on which the petitioner relies, and that it includes representative data and information known to the petitioner which are known to the petitioner which are unfavorable to the petition.

Respectfully submitted,

Joel Stocker

Joel Stocker March 13, 2007
1221 Brickell Avenue
Miami, FL 33131

Exhibit "A"

Example of Label
for
Non- Sedating Antihistamines

Drug Facts

Active Ingredient (in each tablet) — **Purpose**
Loratadine 10 mg — Antihistamine

Uses
temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
• runny nose • sneezing • itchy, watery eyes • itching of the nose or throat

Warnings
Do not use if you have ever had an allergic reaction to this product or any of its ingredients.
Ask a doctor before use if you have liver or kidney disease. Your doctor should determine if you need a different dose.
When using this product do not take more than directed. Taking more than directed may cause drowsiness.
Stop use and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away.
If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

adults and children 6 years and over	1 tablet daily, not more than 1 tablet in 24 hours
children under 6 years of age	ask a doctor
consumers with liver or kidney disease	ask a doctor

Other information • store at 15°–30°C (59°–86°F) • protect from excessive moisture • safety sealed: do not use if imprinted blister unit is open or torn

Inactive Ingredients lactose monohydrate, magnesium stearate, microcrystalline cellulose, sodium starch glycolate

Questions? call · 24 hours a day, 7 days a week.

Exhibit "B"

Greenberg Traurig

MEMORANDUM

SUBJECT: FDA Authority to Approve a Prescription to OTC Switch Without Sponsor Consent

DATE: March 12, 2007

This memorandum responds to your request for an analysis of whether the Food and Drug Administration ("FDA") is authorized to re-designate classes of approved prescription drugs as over-the-counter ("OTC") even though the sponsors of those drugs (*i.e.*, the holder of the approved New Drug Application ("NDA")) may oppose the re-designation.

Certain pharmaceutical industry trade associations have argued that absent sponsor approval, the FDA lacks the authority to switch a drug from prescription to OTC through rulemaking. According to these critics, FDA can only authorize such a switch following a formal, cumbersome trial-like administrative adjudication. In the alternative, they argue that even if rulemaking is appropriate, the FDA cannot use informal, notice-and-comment rulemaking, but instead must use formal, hearing-based rulemaking. These same critics have also argued that even if a drug could be switched through informal rulemaking, the FDA lacks the authority to reference the sponsor's safety and efficacy data to support the rulemaking.

None of these arguments is facially correct. First, the Food, Drug, and Cosmetic Act ("FD&C Act") expressly authorizes the Secretary of Health and Human Services ("Secretary") to switch a drug from prescription to OTC following rulemaking. There is no statutory provision that even suggests, let alone requires, that rulemaking in this setting must give way to an adjudication, *i.e.*, formal trial-like proceeding.

Second, unless there is a statutory provision to the contrary, the courts have consistently held that an agency is free to undertake any type of rulemaking it deems appropriate. Here, there is nothing that would interfere with that agency prerogative.

Third, there is nothing in the FD&C Act[1], the Freedom of Information Act ("FOIA"), or any other federal law that would preclude the agency from making regulatory decisions about a drug based on drug-specific data submitted to it by the drug's sponsor. While the FD&C Act and FOIA may limit public disclosure of these

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[1] The FD&C Act does prevent an "applicant" from referencing another manufacturer's safety and efficacy for various lengths of time under various circumstances. *See* FD&C Act §§ 505(b), (c), and (j). However, these provisions are not relevant here, because a drug "applicant" is not seeking to reference safety and efficacy data.

data, they in no way affect the ability of the FDA to use the data as part of a rulemaking. One cannot equate "use" of data by the agency with public disclosure. In short, a decision concerning whether to switch a product from prescription to OTC is committed to agency discretion and should be based on the scientific merit of the petition and not hindered by artificial legal constraints that nowhere appear in federal law.

Analysis

I. FDA May Properly Use Informal Rulemaking to Switch a Drug from Prescription to Over-the-Counter

Those who oppose citizen or FDA initiated Rx to OTC switches first argue that the FDA lacks the legal authority to initiate a switch over the objections of the holder of the NDA without providing the holder with a full evidentiary trial-like hearing in the form of an adjudication. The OTC opponents argue that a switch without the concurrence of the NDA holder may not be accomplished through informal, notice-and-comment rulemaking for three reasons. First, they argue rulemaking is not appropriate in this setting and that an adjudication is required by FD&C Act § 505(e). Second, they argue that if rulemaking is to be used, a formal, hearing-based rulemaking is required by the Administrative Procedure Act ("APA"), Pub. L No. 79-404, 60 Stat. 237, codified in part at 5 U.S.C. §§ 551 *et seq.*, and principles of due process, where, as here, the proposed rule is aimed at a single entity (*i.e.*, the holder the NDA). The OTC opponents misconceive the nature of the FD&C Act and the APA.

A. Administrative Procedure Act—an Overview

The APA, sometimes referred to as the "constitution" for administrative agencies, carefully proscribes how agencies, including the FDA, may act. Generally, the APA divides agency action into two broad categories—rulemaking and adjudication. *See American Airlines, Inc. v. Civil Aeronautics Bd.*, 359 F.2d 624, 629 (D.C. Cir. 1966). An adjudication, within the meaning of the APA, is only required when the organic legislation expressly mandates an adjudication "on the record." 5 U.S.C. § 554. In all other cases, "the choice between rulemaking and adjudication lies in the first instance within the (agency's) discretion." *R.L. Investment Limited Partners v. Immigration and Naturalization Service*, 86 F.Supp.2d 1014 (D. Haw. 2000) (citing *NLRB v. Bell Aerospace Co.*, 416 U.S. 267, 294 (1974)). If the agency either opts for rulemaking or is required by statute to undertake rulemaking, the agency is free, absent a statutory command to the contrary, to select among three types of rulemaking—(1) formal rulemaking, which usually includes some form of hearing, (2) informal, notice-and-comment rulemaking, which is the most common, and (3) negotiated rulemaking, which is relatively rare.

It is against this backdrop that we assess the opponents' claims (i) that an Rx-OTC switch cannot be accomplished by rulemaking and can only be accomplished through adjudication, and (ii) that, even if rulemaking were appropriate, the FDA is precluded from using informal, notice-and-comment rulemaking.

B. The FD&C Act Not Only Expressly Authorizes Rulemaking, But Contains No Provision that Contemplates Adjudication

1. Switch by Rulemaking is Expressly Authorized

It is by now axiomatic that "[t]he starting point of any inquiry into the application of a statute is the language of the statute itself." *Reiter v. Sonotone* Corp., 442 U.S. 330, 337 (1979). Section 503(b)(3) of the FD&C Act states as follows:

> The Secretary may by regulation remove drugs subject to section 505 [NDA, ANDA] from the requirements of paragraph (1) [requiring a prescription] of this subsection when such requirements are not necessary for the protection of the public health. (Emphasis supplied).

On its face, section 503(b)(3) expressly authorizes the Secretary through rulemaking to switch drugs from prescription to OTC. Neither the FD&C Act nor the APA contains any provision limiting the authority of the Secretary to undertake Rx-OTC rulemaking even without the consent of the NDA holder.

Recognizing that the statute is clear on its face, the opponents argue instead that rulemaking is "ill-suited to the development and review of" safety and efficacy data and further, "is an anachronism that has not been used since 1971." Comment of Consumer Healthcare Products Association to FDA at 11 (Aug. 25, 2000) ("Comment"). Whether, as a matter of policy, rulemaking is ill-suited to the task or is an anachronism is not relevant to the issue at hand, namely whether the Secretary has the legal authority to issue a rule switching a product to OTC. Congress has expressly authorized the FDA to switch by rulemaking and that congressional expression governs.

If policy were to be considered, it would be difficult to ignore the strong public policy underlying the rulemaking process; any attempt to undermine that process would necessarily strike at the core of the APA and undermine its broad provisions encouraging wide public participation. "Section 553(e) of the APA requires agencies to give interested parties the right to petition for the issuance, amendment, or repeal of a rule." *National Wrestling Coaches v. Dept. of Education*, 366 F.3d 930, 948, *reh'g denied,* 383 F.3d 1047 (D.C. Cir. 2004). FDA has detailed regulations implementing the right of a citizen under the APA to petition for rulemaking. *See* 21 CFR § 10.30. There is nothing in the prescription requirements of the FD&C Act that in any way affects those rights. *See* Durham-Humphrey Act of 1951, Pub. L. No. 82-215, 65 Stat. 648 (1951).

2. Switch by Rulemaking, as Opposed to Adjudication, is Appropriate

The opponents also argue that an agency action aimed at a small cohort of persons cannot be accomplished through rulemaking. In particular, they argue that "fundamental principles of administrative law and due process require . . . the use a formal hearing process for switch rules . . . regardless of the applicability of section 505(e), because the switch regulation constitutes an individual adjudication requiring a formal hearing."

Comment at 12 (emphasis supplied). The opponents are confusing a number of distinct principles: hearing, adjudication, and rulemaking.

Adjudication involves a hearing and much more. It is a formal trial-like procedure involving ten elemental safeguards, *e.g.*, notice, opportunity to confront, oral presentation, cross-examination. *See Goldberg v. Kelly*, 397 U.S. 254, 266 (1970). It is only required, as noted above, where the organic legislation expressly requires an adjudication "to be determined on the record after opportunity for an agency hearing." 5 U.S.C. § 554. A hearing, in contrast, can be used either as part of an adjudication or as part of formal rulemaking. A hearing is only required in rulemaking where the organic legislation, in this case the FD&C Act, expressly requires it. Correspondingly, an adjudication, which necessarily involves a hearing and much more, is only triggered where the statute requires it. Therefore, the notion that an adjudication is required "as a fundamental principle of administrative law" is simply incorrect. It is only required where it is expressly required by statute. *See Meriden Community Action Agency v. Shalala*, 880 F.Supp. 882 (D.D.C. 1995), *affirmed per curiam*, 80 F.3d 524 (D.C. Cir. 1996); *Abbs v. Sullivan*, 756 F.Supp. 1172 (W.D. Wis. 1990), *vacated on other grounds*, 963 F.2d 918 (7th Cir. 1992).

The opponents also suggest that rulemaking, of any sort, is inappropriate where the class of persons affected is small; instead, they suggest that an adjudication ought to be used. The opponents misconceive rulemaking. Adjudication, as noted above, is only necessary where required by statute. In all other cases, rulemaking is the default and carries "presumptive procedural validity . . . , unless countermanded by different Congressional mandate." *American Airlines, Inc. v. Civil Aeronautics Bd.*, 359 F.2d at 630. Rulemaking is appropriate here for a variety of independent reasons. First, as noted above, the FD&C Act expressly authorizes the Secretary to use rulemaking as the vehicle to permit the sale of a drug OTC. *See* FD&C Act § 503(b)(3).

Second, the definition of "rule" easily encompasses an order switching a prescription drug to an OTC drug. In particular, a "rule" is broadly defined as the "whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy . . . ." 5 U.S.C. § 551(4). Even if there were no express statutory authorization to switch via rule, the switch certainly could still be accomplished through rulemaking because any switch would be of "particular applicability" and "future effect" and designed to implement the law. The fact that it may affect one or two companies is simply not relevant. Indeed, Congress expressly inserted the phrase "particular applicability" to ensure that agencies could promulgate rules aimed at addressing a single person or small class of individuals. *See* H. R. Rep. No. 1980, 79th Cong., 2d Sess., at 283 n.1 (1946). There must be "relative certitude before a court concludes that adjudicatory procedures are required." *American Airlines, Inc. v. Civil Aeronautics Board*, 359 F.2d at 630. Here, not only is there no statutory provision requiring an adjudication, but an adjudication would be inappropriate. "In adjudication, retroactivity is the norm," and as such, it is usually reserved for instances where an agency seeks to impose a sanction for past wrongs. *Motion Picture Ass'n of Am. v. Oman*, 969 F.2d 1154, 1155 (D.C. Cir. 1992). In rulemaking, by definition, retroactivity is the exception; rules are intended to have future effect and do

not impose disabilities based on past conduct. *See Bowen v. Georgetown Univ. Hosp.*, 424 U.S. 288 (1988). Here, of course, what the agency seeks to accomplish is purely prospective, not retroactive.

Third, the cases cited by the opponents, which ostensibly support the need for adjudication, are not relevant since in each case, either an adjudication or hearing was required by the organic legislation, which is decidedly not the case here, or the court upheld the agency rulemaking. *See e.g., Civil Aeronautics Bd. v. Delta Airlines*, 367 U.S. 316 (1961) (notice and hearing required by organic legislation); *American Airlines, Inc. v. Civil Aeronautics Bd., supra* (upholding agency rulemaking).

C. The FDA is Authorized Use Informal Rulemaking to Switch from Rx to OTC

1. Section 505(e) Has Nothing To Do With Switching From Prescription to OTC

The opponents contend that even if a switch can accomplished through rulemaking, that rulemaking cannot be informal. Specifically, the opponents relying on FD&C Act § 505(e) suggest that while the agency may use informal, notice-and-comment rulemaking when the NDA holder does not object to the switch, it must use "formal rulemaking" when the holder objects. This suggestion is inconsistent with the language of both the FD&C Act and the APA. In neither statute does the nature of the process depend on the views of the NDA holder.

The APA permits an agency to promulgate a rule using notice-and-comment rulemaking unless "rules are required by statute to be made on the record after opportunity for an agency hearing . . . ." 5 U.S.C. § 553(c). There is nothing in FD&C Act § 503(b)(3) which in any way would suggest that formal, hearing-based, rulemaking is required. Recognizing this, the opponents argue that the hearing requirement is actually to be found in FD&C Act § 505(e), which deals with withdrawing approval of an already approved NDA. Not only does an OTC switch have nothing to do with withdrawing approval of the NDA, none of the requisites that would trigger a hearing under that section pertains here. For example, a hearing is required under section 505(e) where the Secretary proposes to withdraw approval (1) if data show that the drug is unsafe, (2) new clinical evidence when coupled with existing data show that the drug is not safe, (3) new evidence when coupled with existing data show by substantial evidence that the drug is not effective, (4) patent information was not timely filed, (5) the application contains false statements, or (6) new information coupled with existing information shows that the labeling of the drug is false or misleading and remains uncorrected.[2]

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[2] The mere fact that a hearing is required does not mean that either formal rulemaking or an adjudication is required. *See United States v. Florida East Coast Railway Co.*, 410 U.S. 224, 234-35 (1973) (provision authorizing agency to act "after hearing" did not require formal rulemaking).

The irony here, of course, is that section 505(e) was designed to provide a hearing before the agency limited the marketing of a drug by withdrawing its approval. Here, in contrast, the agency is contemplating increasing the marketability of a drug by reducing agency-imposed restrictions. In short, not only does section 505(e) not speak to the prescription-OTC switch, it is entirely inapplicable and is aimed at ridding the market of dangerous drugs as opposed to increasing the marketability of safe drugs.

2. Switch by Rulemaking is Consistent with Due Process

Finally, the opponents suggest that informal, notice-and-comment rulemaking, *i.e.*, rulemaking without a hearing, would be inconsistent with due process. Due process concerns are only implicated if the opponents are able to point to a protected property interest. *See Lujan v. G & G Fire Sprinklers, Inc.*, 532 U.S. 189 (2001); *Board of Regents v. Roth*, 408 U.S. 564 (1972) (holding that a professor's expectation of renewal a one-year contract created no property interest for due process purposes). Here, there is no protected property interest at issue. Assuming that there is a property interest in holding an approved NDA, there is certainly no property interest in agency action which actually makes it easier to sell the product. Simply put, absent a patent, a person has no constitutionally protected property right in maintaining a monopoly or artificially restricting access to its products. To the contrary, a monopoly operating in a highly regulated industry should expect that its business will frequently be affected by government action. *See Connolly v. Pension Benefit Guaranty Corp.*, 475 U.S. 211, 227 (1986); *Yankee Nuclear Power Corp. v. Natural Resources Def. Council, Inc.*, 435 U.S. 519, 541 (1978) (holding that "absent extraordinary circumstances it is improper for a reviewing court to prescribe the procedural format an agency must follow."); *Philip Morris, Inc. v. Harshbarger*, 159 F.3d 670, 679 (1st Cir. 1998); *McAndrews v. Fleet Bank of Mass., N.A.*, 989 F.2d 13, 19 (1st Cir.1993).

Even so, the courts have consistently held that in a regulatory setting such as this, the Due Process Clause requires no more than notice and the opportunity to present evidence or comments.[3] Thus, in *Darrell Andrews Trucking v. Federal Motor Carrier Safety Administration*, 296 F.3d 1120 (D.C. Cir. 2002), plaintiff challenged an agency action which reduced its safety rating by arguing among other things that due process required an evidentiary hearing. In brushing aside this argument, the court noted that the agency "put Andrews on notice of the charges, Andrews had an opportunity to present its arguments through written briefs and . . . [to present other evidence through affidavit]. Procedural due process requires no more in this kind of administrative setting." *Id.* at 1134. Informal rulemaking more than satisfies these minimal due process considerations: it provides notice and the opportunity to present comments and evidence.

[3] The Comment's reliance on *Barry v. Barchi*, 443 U.S. 55 (1979) and *Ingraham v. Wright*, 430 U.S. 651 (1977) is mystifying. In *Barry*, the Court held that the State of New York had to offer a horse trainer a prompt hearing after suspending him for doping a horse in a race. In *Ingraham*, the Court held that due process does not require notice and hearing prior to imposing corporal punishment in public schools. Neither case had anything to do with the rulemaking and neither case involved federal agencies or the APA.

II. FDA May Use a Sponsor's Safety and Effectiveness Data as Part of a Rulemaking to Switch the Drug From Prescription to OTC

The opponents also argue that even if the FDA has the statutory authority to accomplish a switch through informal rulemaking, it is effectively precluded from doing so because it lacks the statutory authority to use the NDA holder's safety and effectiveness data without the consent of the NDA holder. In particular, one opponent has argued that if the FDA were to rely on the NDA holder's data without its permission and "without following the procedures set forth in the Hatch-Waxman Act," the agency would be "violat[ing] the sponsor's proprietary rights to its data." Comment at 10. This opponent then goes on to point out in a footnote that the FDA could not "release safety and effectiveness data from the prescription NDA, because these constitute confidential commercial information exempt from release under the Freedom of Information . . . ." Comment at 10-11 n.12.

These arguments may hold some theoretical or academic fascination for a few, but they have nothing to do with either the use of data by the FDA as part of a rulemaking process or the ability of a citizen petitioner to submit its own safety and efficacy data. Indeed, the opponents never question the propriety of latter. As to the former, there is nothing in the FD&C Act or the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, that would in any way preclude FDA from relying on an NDA holder's safety and efficacy as part of a rulemaking.

The FD&C Act provides limited protection to a sponsor's clinical data. Section 505(l), added by Hatch-Waxman, requires the FDA, upon request, to disclose "[s]afety and effectiveness data and information" submitted by the NDA holder as part of its application that was subsequently abandoned by the sponsor, "unless extraordinary circumstances are shown." FD&C Act § 505(l). This data protection provision is limited on its face. It merely authorizes the FDA to restrict public disclosure; it does not prevent the FDA from using the NDA's holder's safety and effectiveness data for regulatory purposes; indeed, those very data have been submitted as part of a regulatory process with the expectation that the agency would use the data for making a regulatory determination. To permit the agency to use the data for one regulatory purpose, but not for another makes no sense and finds no support in federal law.

Moreover, the FDA is required to make a detailed summary of the safety and effectiveness data available to public upon request. *See* 21 CFR § 314.430. These publicly available summaries when coupled with petitioner-conducted studies can form the basis of substantively complete citizen's petition to switch from prescription to OTC. In short, FDA is not required to blind itself to an NDA holder's safety and effectiveness when considering a citizen's petition to switch; correspondingly, the citizen petitioner is permitted by FDA regulations to have access to summaries of those data.

Interestingly, it is not altogether clear that a sponsor's safety and efficacy data are automatically exempt from disclosure. Section 505(l), much like the FOIA, does not require the agency to keep safety and effectiveness under wraps. To the contrary, both

section 505(l) and FOIA place the decision to disclose within the discretion of the agency. FOIA, for example, requires each agency to make available to the public agency records.. *See* 5 U.S.C. § 552(a)(3). This mandate to make records available does not apply if, for instance, the agency determines that the records are "commercial and confidential." 5 U.S.C. § 552(b)(4) ("Exemption 4"). The agency, however, is not precluded by Exemption 4 from releasing commercial information. Exemption 4 merely forms the basis on which the agency can decline to make that information publicly available. Even if the agency agrees that the information falls within Exemption 4, that does not end the inquiry, especially with respect to safety and effectiveness data. *See Niagara Mohawk Power Corp. v. Dept of Energy*, 169 F.3d 16, 18 (D.C. Cir. 1999) (holding that "the agency has the burden of showing that requested information comes within a FOIA exemption."). Information that a person is required to submit to the Government, such as safety and effectiveness data, is considered confidential only if its disclosure is likely either "(1) to impair the Government's ability to obtain necessary information in the future; or (2) to cause substantial harm to the competitive position of the person form whom the information was obtained." *Public Citizen Research Group v. Food and Drug Administration*, 185 F.3d 898, 903 (D.C. Cir. 1999) (concluding that some safety and effectiveness data qualified as exempt from disclosure, but some did not).

In short, neither the FD&C Act nor FOIA precludes the FDA from using a sponsor's clinical data for rulemaking purposes. The use of data by the agency is simply not the equivalent of "public disclosure." Indeed, the entire clinical data issue may be a red herring; many have argued that the type of data necessary to support a switch may be profoundly different than the type of data necessary to support an NDA approval. *See* Kevin J. Kraushaar, Market Exclusivity After a Prescription to Nonprescription Drug Switch: Striking the Right Balance Between Innovation and Competition, 54 FOOD AND DRUG L. J. 243 (1999).