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VIA HAND DELIVERY

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Enforce the FDC Act to Prevent the Use of REMS to Block or Delay Generic Competition

Dear Sir or Madam:

CITIZEN PETITION

Dr. Reddy's Laboratories, Inc. ("Dr. Reddy's") submits this Citizen Petition pursuant to the Federal Food, Drug, and Cosmetic Act ("FDC Act") and the Food and Drug Administration's ("FDA's") implementing regulations at 21 C.F.R. § 10.30 to request that FDA establish procedures to facilitate the availability of generic versions of drug products subject to a Risk Evaluation and Mitigation Strategy ("REMS") and enforce the FDC Act to prevent companies from using REMS to block or delay generic competition. Dr. Reddy's also requests that FDA work with the Federal Trade Commission ("FTC") in an effort to prevent anti-competitive REMS abuses.

As discussed below, Dr. Reddy's is concerned that REMS, which were created under the FDA Amendments Act, Pub. L. No. 110-85 (enacted Sept. 27, 2007) ("FDAAA"), while a useful tool to "ensure that the benefits of the drug outweigh the risks of the drug," FDC Act § 505-1(a)(1), can also be used improperly to prevent or delay generic competition. Specifically, REMS can be used as an excuse by New Drug Application ("NDA") sponsors for providing generic companies with drug product sample needed to conduct bioequivalence testing and for other purposes required by FDA. Dr. Reddy's recent experience in attempting to obtain biostudy sample of a drug product under a so-called "deemed REMS" has borne out this concern. In that case, after sending multiple requests to purchase biostudy drug product sample, Dr. Reddy's was ultimately told by the NDA holder that the company "has no obligation to supply Dr. Reddy's . . . and declines to do so."

FDA-2009-P-0266-0001 CP

The number of drug products subject to REMS is growing.[1] And unless FDA takes swift action now by exercising the authority that Congress granted the Agency under the FDC Act to prevent REMS gaming, consumers will be prevented from having timely access to generic versions of an increasing number of important drugs. Moreover, the use of REMS to prevent generic competition upsets the careful balance Congress intended when it passed the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) ("Hatch-Waxman Amendments") by permitting an additional *de facto* and unearned period of market exclusivity to NDA holders.

I. ACTION REQUESTED

This Citizen Petition requests that FDA:

(1) Promptly issue a Compliance Policy Guide ("CPG") or guidance document establishing a procedure whereby a generic applicant who seeks to obtain a sufficient quantity of a listed drug subject to a REMS (that incorporates elements to assure safe use that restrict product distribution) to conduct bioequivalence testing (and to meet other FDA requirements) can obtain a letter from FDA describing the Agency's findings that such generic applicant has agreed to applicable restrictions on distribution of the listed drug necessary to assure safe use of the drug product during bioequivalence testing;

(2) Incorporate into REMS that restrict product distribution, including those REMS currently under review for "deemed REMS" products, a provision stating that the listed drug sponsor will not to use REMS restricted distribution elements to assure safe use to delay or block generic competition;

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[1] FDA has approved 49 REMS for new drugs approved since the enactment of FDAAA, and has requested REMS for many other products. See FDA, Approved REMS, http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111350.htm (last updated May 30, 2009). In addition, pursuant to FDAAA § 909(b)(1), many products approved prior to the enactment of FDAAA are deemed to have in effect an ***approved*** REMS. See FDA, Notice, Identification of Drug and Biological Products Deemed to Have REMS for Purposes of FDAAA of 2007, 73 Fed. Reg. 16,313 (Mar. 27, 2008) ("Drug and biological products deemed to have in effect an approved REMS are those that on March 25, 2008 . . . had in effect 'elements to assure safe use.'"). Sponsors of "deemed REMS" products were required to submit a proposed REMS to FDA by September 21, 2008. See FDAAA § 909(b)(3).

(3) Enforce the FDC Act against sponsors of listed drugs subject to an approved restricted distribution REMS, including, to the extent possible, against those sponsors of "deemed REMS" products who, notwithstanding having received a copy of a letter identified in (1) above, have refused (either explicitly or constructively) to sell, at fair market value, a sufficient quantity of their drug product to a proposed generic applicant for bioequivalence testing purposes; and

(4) Refer to the FTC any complaints received from generic drug manufacturers alleging that the sponsor of a listed drug subject to an approved restricted distribution REMS has used such REMS in an anti-competitive manner to delay or block generic competition.

I. STATEMENT OF GROUNDS

A. Factual Background

1. FDA Approval of Generic Drugs

Under the FDC Act, as amended by the Hatch-Waxman Amendments, in order for FDA to receive an Abbreviated New Drug Application ("ANDA") for a proposed generic version of an innovator drug product, the Agency requires that the application contain, among other things, information showing that the proposed generic drug product is "bioequivalent" to the drug identified in the Orange Book as the Reference Listed Drug ("RLD"). See FDC Act §§ 505(j)(2)(A)(iv), 505(j)(4)(F); 21 C.F.R. §§ 314.94(a)(7), 314.127(a)(6)(i) (providing that FDA will refuse to approve an ANDA if information submitted is insufficient to show that the drug product is bioequivalent to the listed drug referenced in the ANDA). A generic drug product is bioequivalent to the RLD if "the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the [RLD] when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either single dose or multiple doses." FDC Act § 505(j)(8)(B)(i).

The purpose of demonstrating bioequivalence is to determine whether changes in a proposed drug product's formulation or manufacturing affect the rate or extent to which the active ingredient reaches the primary site of action. It is presumed that a drug product containing the identical active ingredient will behave in the same way as the RLD if it reaches the primary site of action at the same rate and to the same extent as the RLD. See

21 C.F.R. § 320.1(e). FDA has considerable discretion in establishing the appropriate drug product-specific methods for a generic applicant to demonstrate bioequivalence. For products that because of their inherent toxicity could be harmful, Dr. Reddy's understands that FDA typically determines that an effective way to ensure the safety of subjects in proposed investigations regarding the bioequivalence of such drugs is to require generic applicants to submit an Investigational New Drug Application to the Office of Generic Drugs ("OGD"), or to otherwise provide OGD with sufficient assurance that the bioequivalence study will be conducted in such a manner as to ensure the safety of the study subjects. Such safeguards, Dr. Reddy's understands, represent a permissible substitute for controls present under a REMS.

In vivo testing is FDA's preferred method for an ANDA applicant to demonstrate bioequivalence (and for a 505(b)(2) applicant to measure bioavailability[2]), but it is not the only permissible method. FDA's regulations state that "[b]ioavailability may be measured or bioequivalence may be demonstrated by several in vivo and in vitro methods," which are described at 21 C.F.R. § 320.24 in descending order of accuracy, sensitivity, and reproducibility.

In addition to conducting any required bioequivalence testing between a proposed generic drug product (i.e., test article) and the RLD, FDA's regulations require the responsible party conducting bioequivalence testing to retain a reserve sample of each test article and RLD used to perform in vivo or in vitro bioequivalence studies that is representative of each batch of the test article and RLD used for testing. See 21 C.F.R. §§ 320.38, 320.63. The reserve samples must "consist of a sufficient quantity to permit FDA to perform five times all of the release tests required in the application or supplemental application." Id. § 320.38(c).

For many drug products, a sufficient amount of the RLD for a generic applicant to conduct FDA-required bioequivalence testing (as well as retained samples) can be procured using normal distribution channels; for example, through drug product wholesalers. A drug product under a REMS, however, may be subject to certain distribution restrictions that significantly limit drug product availability and prevent a prospective generic applicant from obtaining a sufficient quantity of the drug product to conduct required bioequivalence testing and for retained samples. For example, Celgene Corporation's ("Celgene's") REVLIMID (lenalidomide) Capsules and THALOMID

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[2] Although this Citizen Petition is specifically directed at generic applicants seeking approval of an ANDA, the issues identified in this petition are also relevant to 505(b)(2) applicants who plan to rely on FDA's previous findings of safety and effectiveness for a listed drug.

(thalidomide) Capsules, both of which are "deemed REMS" products[3] and are known human teratogens, are tightly controlled under detailed restricted distribution programs. In the case of REVLIMID, that program is known as the RevAssist^{SM} program. Under the RevAssist^{SM} program, REVLIMID is prescribed, received, and dispensed only after the physician, patient, and pharmacy involved are all registered in the program. REVLIMID is not distributed through wholesalers and is not given to physicians via samples. In the case of THALOMID, the restricted distribution program is known as the S.T.E.P.S.® program (i.e., System for Thalidomide Education and Prescribing Safety). As with the REVLIMID RevAssist^{SM} program, THALOMID, under the S.T.E.P.S.® program, is prescribed, received, and dispensed only after the physician, patient, and pharmacy involved are all registered in the program. THALOMID is similarly not distributed through wholesalers and is not given to physicians via samples.

2. REMS Requirements and Elements to Assure Safe Use

FDAAA amended the FDC Act to add § 505(p), which states:

> A person may not introduce or deliver for introduction into interstate commerce a new drug if –
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> (A)(i) the application for such drug is approved under [FDC Act § 505(b) or (j)] and is subject to section 503(b) . . . and
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> (B) a [REMS] is required under section 505-1 with respect to the drug and the person fails to maintain compliance with the requirements of the approved strategy or with other requirements under section 505-1, including requirements regarding assessments of approved strategies.

FDC Act § 505(p).

FDC Act § 505-1 provides FDA with the authority to require a proposed REMS from an NDA sponsor if the Agency determines that such a strategy "is necessary to ensure that the benefits of the drug outweigh the risks of the drug." FDC Act § 505-1(a)(1). FDA may also require a REMS for a previously approved covered application if the Agency "becomes aware of new safety information and makes a determination that

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[3] Pursuant to FDAAA § 909, all drug products approved before March 25, 2008 with elements to assure safe use (either required under 21 C.F.R. § 314.520, or otherwise agreed to by the sponsor) are deemed to have in effect an approved REMS. See 73 Fed. Reg. at 16,314 (Mar. 27, 2008).

such a strategy is necessary to ensure that the benefits of the drug outweigh the risks of the drug." Id. § 505-1(a)(2).

Under FDC Act § 505-1(f), FDA may require that a REMS "include such elements as are necessary to assure safe use of the drug, because of its inherent toxicity or potential harmfulness." FDC Act § 505-1(f)(1). The elements to assure safe use of such a drug include, among other things, certain restricted distribution, procurement, and dispensing systems. For example, one element to assure safe use is that "the drug be dispensed to patients only in certain health care settings, such as hospitals." Id. § 505-1(f)(3)(C). Another is that "the drug be dispensed to patients with evidence or other documentation of safe-use conditions, such as laboratory test results." Id. § 505-1(f)(3)(D). Several drug products, including REVLIMID and THALOMID, are subject to an approved REMS incorporating elements to assure safe use restrictions that limit their availability, such that generic drug manufacturers cannot procure drug product sample through normal distribution channels.

In developing REMS, Congress directed FDA to, among other things, ensure that elements to assure safe use "not be unduly burdensome on patient access to the drug," FDC Act § 505-1(f)(2)(C), and, in an effort "to minimize the burden on the health care delivery system," id. § 505-1(f)(2)(D), design elements to assure safe use that are "compatible with established distribution, procurement, and dispensing systems . . . ." Id. § 505-1(f)(2)(D)(ii). In addition, FDA, through the Agency's Drug Safety and Risk Management Advisory Committee, must seek public input about how elements to assure safe use can be standardized "so as not to be – (i) unduly burdensome on patient access to the drug; and (ii) to the extent practicable, minimize the burden on the health care delivery system." Id. § 505-1(f)(5)(A). FDA must then, at least annually, evaluate and assess whether elements to assure safe use on one or more drugs meet these goals, and must issue or modify Agency guidelines – or modify elements to assure safe use – to meet such goals. See id. § 505-1(f)(5)(B)-(C).

Recognizing the potential that REMS restricted distribution programs could be used to block or delay generic competition, Congress included in FDAAA a provision amending the FDC Act mandating that REMS elements to assure safe use not be used as an obstacle to generic drug approval. Specifically, FDC Act § 505-1(f)(8) states:

> ***No holder of an approved covered application shall use any element to assure safe use*** required by [FDA] under [FDC Act § 505-1(f)] ***to block or delay approval of an application under section 505(b)(2) or (j)*** or to prevent application of such element under [FDC Act § 505-1(i)(1)(B)] to a drug that is the subject of an [ANDA].

FDC Act § 505-1(f)(8) (emphasis added).

FDAAA also amended the FDC Act to create new provisions for the enforcement of § 505-1. Specifically, under new FDC Act § 502(y), a drug is deemed to be misbranded "[i]f it is a drug subject to an approved [REMS] pursuant to section 505(p) and the responsible person (as such term is used in section 505-1) ***fails to comply with a requirement of such strategy provided for under subsection*** (d), (e), or ***(f) of section 505-1***." FDC Act § 502(y) (emphasis added). In addition, FDAAA amended the law to add new § 303(f)(4), which states that "[a]ny responsible person (as such term is used in section 505-1) ***that violates a requirement of section*** 505(o), 505(p), or ***505-1*** shall be subject to a civil monetary penalty" of up to $10 million for all violations adjudicated in a single proceeding. FDC Act § 303(f)(4)(A) (emphasis added).

With respect to the enforcement of these provisions for a product deemed to have an approved REMS in effect, FDAAA states that such a product "is subject to enforcement by [FDA] to the same extent as any other [REMS] under [FDC Act § 505-1], except that [FDC Act §§] 303(f)(4) and 502(y) . . . shall not apply to such strategy before [FDA] has completed review of, and acted on, the first assessment of such strategy under [FDC Act § 505-1]." FDAAA § 909(b)(2)(B).

FDA has not yet, to Dr. Reddy's knowledge, used its new statutory authority to take enforcement action against a responsible person for failing to comply with a REMS requirement under the FDC Act, either generally or specifically with respect to FDC Act § 505-1(f)(8).

B. Delaying Generic Competition Through REMS Gaming

REMS requirements that restrict distribution, procurement, and dispensing of a drug product can be used to block or delay generic competition. Indeed, Dr. Reddy's recent attempts to procure a sufficient quantity of REVLIMID from Celgene for bioequivalence testing purposes is one recent case in which the company believes this occurred. Another recent example concerns Barr Laboratories, Inc.'s ("Barr's") attempts to procure drug product sample for another Celgene drug product – THALOMID.

In August 2008, Dr. Reddy's sent a letter to Celgene requesting that the company provide REVLIMID to Dr. Reddy's for bioequivalence study testing purposes. Dr. Reddy's agreed to reimburse Celgene for the fair market value of the requested REVLIMID drug product, as well as any shipping costs. In addition, Dr. Reddy's assured Celgene that Dr. Reddy's procedures for conducting any required testing

involving lenalidomide and the REVLIMID drug product provided by Celgene will fully comply with FDA requirements, and that Dr. Reddy's controls with respect to lenalidomide will be comparable to the RevAssist[SM] program. Dr. Reddy's requested a timely response to the company's request. Celgene did not respond.

Dr. Reddy's sent a second letter to Celgene in December 2008. In addition to repeating the company's request for biostudy drug sample and offering to pay Celgene the fair market value of the requested REVLIMID drug product, Dr. Reddy's reminded Celgene that FDC Act § 505-1(f)(8) prevents a company from using a REMS to block or delay generic competition, and that Celgene's failure to provide the requested sample quantity could result in Dr. Reddy's seeking a remedy from FDA and/or the FTC. Celgene finally responded to Dr. Reddy's letters in January 2009. Celgene's 1-page response dismisses Dr. Reddy's biostudy sample request in a single sentence: "Celgene has no obligation to supply Dr. Reddy's with REVLIMID and declines to do so." Letter from Maria E. Pasquale, Vice President and Chief Counsel, Celgene, to Jennifer K. Benneson, Vice President, Legal Affairs, Dr. Reddy's (Jan. 12, 2009) (Attachment #1).

Celgene's efforts to block generic competition with respect to REVLIMID appear to be part of a company-wide campaign to block generic competition for its drug products. Indeed, Celgene has taken similar types of actions with respect to THALOMID. In patent infringement litigation against Barr concerning Barr's submission of ANDA No. 78-505 (which is currently pending at FDA), Barr has asserted counterclaims that include tortious interference with a prospective business relationship and/or economic advantage, monopolization, attempted monopolization and conspiracy to monopolize, and conspiracy in restraint of trade. Barr's counterclaims revolve primarily around the allegation that Celgene unlawfully interfered with Barr's relationship with a third party supplier of thalidomide called Seratec. According to Barr:

> While negotiating with [Barr] to execute a thalidomide supply agreement, Seratec entered an exclusive supply arrangement with Celgene, whereby Seratec agreed to supply thalidomide [Active Pharmaceutical Ingredient ("API")] to Celgene alone and not to any other company. Seratec refused to supply [Barr] with thalidomide API or provide a [Drug Master File] reference letter on [Barr's] behalf because of the exclusive thalidomide API supply agreement Seratec executed with Celgene.

Barr Laboratories, Inc., Answer, Counterclaims and Demand for Jury Trial at 43, Celgene Corp. v. Barr Labs., Inc., CA No. 07-286 (D.N.J. Mar. 1, 2007) (Attachment #2). Barr alleges that "Celgene required Seratec to enter into an exclusive supply agreement with it

for the purpose of interfering with another company's ability to market a thalidomide product," id., and that Barr's ANDA was significantly delayed while the company searched for an alternative supply of drug product and conducted new bioequivalence studies. See id. at 43-44.

In turn, Celgene submitted a citizen petition to FDA requesting that the Agency not approve Barr's ANDA because, among other things, it raises unacceptable safety risks insofar as Celgene's S.T.E.P.S.® program is concerned, see Citizen Petition of Celgene, FDA Docket No. 2007-P-0113-0002, at 1-2 (Sept. 20, 2007). Celgene also alleged in its patent infringement litigation against Barr that Barr engaged in illegal or inequitable conduct by obtaining drug product necessary for Barr to conduct bioequivalence testing not in accordance with Celgene's S.T.E.P.S.® program. Specifically, Celgene alleges that:

> Barr, in an effort to obtain Thalomid® for use in its ANDA application, obtained 280 capsules of the 50mg, 140 capsules of the 100mg, and 924 capsules of the 200mg Thalomid® in violation of the product labels and S.T.E.P.S.® system by improperly purchasing the drug from a pharmacy. Upon information and belief, Barr did not attempt to obtain the drug in accordance with the FDA-mandated S.T.E.P.S.® system.

Reply to Counterclaims at 25, Celgene Corp. v. Barr Labs., Inc., CA No. 07-286 (D.N.J. Apr. 5, 2007) (Attachment #3).

In other words, a company can tie up the supply of a REMS restricted distribution drug product, thereby forcing a generic manufacturer to find alternative means of obtaining the RLD product – that Celgene, for example, has stated to Dr. Reddy's it "has no obligation to supply" – only to be faced with allegations that it unlawfully procured the drug product. Such efforts are nothing more than crude attempts to delay or block generic competition and clearly violate the REMS anti-gaming statutory provision at FDC Act § 505-1(f)(8).

Moreover, the use of REMS to prevent generic competition upsets the delicate balance between innovator intellectual property protection interests and timely generic entry into the market that Congress intended when it passed the Hatch-Waxman Amendments by permitting NDA holders to manipulate the REMS requirements to obtain a *de facto* and unwarranted period of market exclusivity.[4] The abuse of REMS as

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[4] See, e.g., Mylan Pharm., Inc. v. Thompson, 268 F.3d 1323, 1326 (Fed. Cir. 2001) ("These provisions of the Hatch-Waxman Amendments emerged from Congress' efforts

a lifecycle management tool to block or delay generic competition is in the same vein as other efforts (e.g., multiple 30-month stays and citizen petitions) some companies have used to extend marketing protections and that have upset the balance of the Hatch-Waxman Amendments. Those and other anti-competitive efforts, many of which the FTC has commented on and objected to, have been, to a large extent, remedied by subsequent amendments to the FDC Act. In the case of REMS gaming, however, Congress had the foresight to predict that REMS could be used to adversely affect generic competition and handed FDA the tools necessary to prevent REMS abuse.

C. FDA Should Establish Procedures to Facilitate Generic Drug Approval and Enforce the FDC Act to Prevent REMS Gaming

While Dr. Reddy's agrees that certain restrictions are needed to assure the safe use of REVLIMID and THALOMID and other REMS drug products because of their inherent toxicity or potential harmfulness, such restrictions should not be used to prevent generic drug manufacturers from obtaining RLD sample for use in bioequivalence testing necessary to obtain ANDA (or 505(b)(2) application) approval. And companies that use REMS for anti-competitive purposes should not go unchecked. As discussed above, FDA has the authority to take enforcement action when a company games REMS to block or delay generic competition.

In an effort to more clearly describe FDA's regulatory procedures and enforcement procedures and practices with respect to innovator companies that seek to use REMS to block or delay generic competition, Dr. Reddy's requests that FDA issue a CPG or guidance document. Under procedures more fully described in a CPG or guidance document, a generic applicant could obtain a letter from FDA describing the Agency's findings that such generic applicant has agreed to applicable distribution restrictions necessary to assure safe use of the REMS restricted distribution drug product during bioequivalence testing. The generic applicant would provide a copy of that letter to an RLD sponsor with a request to purchase, at fair market value, a sufficient quantity of the REMS drug product for bioequivalence testing purposes. If the RLD sponsor fails to provide the generic applicant with the requested drug product in a timely manner (e.g., within 30 days of receiving a request) notwithstanding FDA's authorization to do so, then FDA should make clear in its CPG or guidance document that the Agency will consider such a failure to be a "use" of a REMS to block or delay generic competition in violation

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to balance two conflicting policy objectives: to induce name brand pharmaceutical firms to make the investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market.") (internal quote and citation omitted).

of FDC Act § 505-1(f)(8), and that enforcement action may be taken consistent with FDC Act §§ 502(y), and 303(f)(4).

Interestingly, Congress suggested a similar procedure in one draft of FDAAA that was passed by the U.S. House of Representatives. That bill – H.R. 2900 – included the following provisions:

> (5) LIMITATION – No holder of an approved application shall use any restriction on distribution required by the Secretary as necessary to assure safe use of the drug to block or delay approval of an application under section 505(b)(2) or (j) or to prevent application of such restriction under subsection (i)(1)(B) to a drug that is the subject of an abbreviated new drug application.
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> (6) BIOEQUIVALENCE TESTING – Notwithstanding any other provisions in this subsection, the holder of an approved application that is subject to distribution restrictions required under this subsection that limit the ability of a sponsor seeking approval of an application under subsection 505(b)(2) or (j) to purchase on the open market a sufficient quantity of drug to conduct bioequivalence testing shall provide to such a sponsor a sufficient amount of drug to conduct bioequivalence testing if the sponsor seeking approval under section 505(b)(2) or (j) –
>
> > (A) agrees to such restrictions on distribution as the Secretary finds necessary to assure safe use of the drug during bioequivalence testing; and
> >
> > (B) pays the holder of the approved application the fair market value of the drug purchased for bioequivalence testing.
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> (7) LETTER BY SECRETARY– Upon a showing by the sponsor seeking approval under section 505(b)(2) or (j) that the sponsor has agreed to such restrictions necessary to assure safe use of the drug during bioequivalence testing, the Secretary shall issue to the sponsor seeking to conduct bioequivalence testing a letter that describes the Secretary's finding which shall serve as proof that the sponsor has satisfied the requirements of subparagraph (6)(A).

H.R. 2900, 110th Cong. § 901 (2007) (as passed by the House of Representatives, July 16, 2007).

Although FDAAA included only section (5) above (i.e., FDC Act § 505-1(f)(8)), clearly Congress was concerned about the potential to game REMS to adversely affect generic competition and anticipated a need for FDA to develop procedures for generic companies to obtain bioequivalence testing supply.[5] FDA should do so now, and should take immediate enforcement action against a company that fails to provide biostudy drug product sample in light of FDA's authorization to do so.

Dr. Reddy's recognizes that FDAAA § 909(b)(2)(B) limits FDA's authority to take enforcement action with respect to a product under a "deemed REMS;" however, the law also states that such a product "is subject to enforcement by [FDA] ***to the same extent as any other [REMS] under [FDC Act § 505-1]***." FDAAA § 909(b)(2)(B) (emphasis added). As such, if FDA finds that a "deemed REMS" product sponsor has violated FDC Act § 505-1, then the Agency should take other appropriate enforcement action not specifically precluded by FDAAA § 909(b)(2)(B) to influence the sponsor's anti-competitive commercial activities. For example, FDA could issue a Warning Letter or Untitled Letter to the sponsor of a REMS product if that sponsor has delayed or blocked generic competition in violation of FDC Act § 505-1(f)(8), because, for example, such sponsor has failed to provide biostudy drug product sample in light of FDA's authorization to do so.

In addition to establishing procedures for generic applicants to obtain drug product sample for bioequivalence testing purposes, FDA should incorporate into the Agency's REMS with sponsors a provision stating that, consistent with FDC Act § 505-1(f)(8), the listed drug sponsor will not to use REMS elements to assure safe use that restrict product distribution to delay or block generic competition. A company that nevertheless uses a REMS to delay or block generic competition should be subject to immediate enforcement action. Incorporating such information into REMS would help ensure that FDA is meeting Congress' directive that elements to assure safe use "not be unduly burdensome on patient access to the drug," FDC Act § 505-1(f)(2)(C), and that such elements are "compatible with established distribution, procurement, and dispensing systems . . . ." Id. § 505-1(f)(2)(D)(ii).

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[5] Dr. Reddy's understands that FDA's current policy is to follow similar procedures when a generic applicant requests the Agency's assistance in obtaining sample of a drug product under a restricted distribution program for bioequivalence testing purposes; however, that policy is not, to Dr. Reddy's knowledge, incorporated into any written and publicly available FDA procedures. Congress' decision not to include the procedures described in H.R. 2900 should not, therefore, be interpreted as a rejection of the actions Dr. Reddy's requests in this Citizen Petition.

Finally, because of the anti-competitive effects of REMS gaming, FDA should refer any complaint the Agency receives about alleged REMS gaming to the FTC. The FTC can then determine whether or not it is appropriate to take enforcement action under the laws and regulations the Commission enforces.

III. ENVIRONMENTAL IMPACT

Pursuant to 21 C .F.R. § 25.31, an environmental impact statement is not required for this action because the grant of the Citizen Petition would not have an effect on the environment.

IV. ECONOMIC IMPACT

Information on the economic impact of the action requested by this Citizen Petition will be submitted if requested by FDA.

CERTIFICATION

Dr. Reddy's makes the following certification pursuant to FDC Act § 505(q)(1)(H): I certify that, to my best knowledge and belief: (a) this petition includes all information and views upon which the petition relies; (b) this petition includes representative data and/or information known to the petitioner which are unfavorable to the petition; and (c) I have taken reasonable steps to ensure that any representative data and/or information which are unfavorable to the petition were disclosed to me. I further certify that the information upon which I have based the action requested herein first became known to the party on whose behalf this petition is submitted on or about the following date: January 2009. If I received or expect to receive payments, including cash and other forms of consideration, to file this information or its contents, I received or expect to receive those payments from the following persons or organizations: DRDr. Reddy's. I verify under penalty of perjury that the foregoing is true and correct as of the date of the submission of this petition.[6]

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[6] FDA has clarified that the citizen petition procedures at FDC Act § 505(q) apply to petitions that affect an ANDA or 505(b)(2) application that is pending at the time the citizen petition is submitted to FDA. See, FDA, Draft Guidance for Industry, Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act, at 4 (Jan. 2009). Dr. Reddy's does not – and cannot as a result

DR. REDDY'S

Respectfully submitted,

Kumar Sekar, Ph.D.
Senior Director
Regulatory Affairs and Compliance

cc: Gary J. Buehler
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Elizabeth H. Dickinson, Esq.
Kim E. Dettelbach, Esq.
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Jon Liebowitz
Chairman, FTC

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of Celgene's refusal to provide drug product so that Dr. Reddy's can conduct the required bioequivalence testing to submit an ANDA – have an ANDA pending at FDA for a generic version of REVLIMID or another drug product subject to a REMS restricted distribution requirement. Nevertheless, Dr. Reddy's is aware of at least one pending ANDA – Barr's ANDA No. 78-505 for a generic version of THALOMID – that serves as a basis for FDA to consider this Citizen Petition under § 505(q).