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January 28, 2003

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Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Room 1-23
12420 Parklawn Drive
Rockville, Maryland 20857

CITIZEN PETITION

The undersigned submit this petition under Section 505 of the Federal Food, Drug, and Cosmetic Act (FDC Act) and 21 C.F.R. § 10.30 and § 314.122 to request the Commissioner of Food and Drugs and the U.S. Food and Drug Administration (FDA) to remove scientifically unwarranted hurdles that are blocking approval of generic versions of Skelaxin® (metaxalone) tablets, sponsored by Elan Pharmaceuticals (Elan). This petition is submitted on behalf of Eon Labs, Inc. (Eon Labs), 227-15 N. Conduit Avenue, Laurelton, NY 11413, a publicly traded corporation that manufactures and distributes generic drug products.

A. ACTION REQUESTED

Eon Labs requests that FDA:

1. a. Amend the labeling for the Skelaxin (metaxalone) tablets to restore labeling required as of May 31, 2002, and before the amendment approved June 20, 2002.

   b. In the alternative, determine pursuant to 21 C.F.R. § 314.122 that the May 31, 2002, labeling for Skelaxin was not withdrawn for safety or effectiveness reasons.

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2. Reverse its March 2002 decision granting Elan's citizen petition, by deleting the requirement for an in vivo bioequivalence study under fed conditions.

3. Delist U.S. Patent No. 6,407,128 from the FDA Orange Book as that patent does not claim an approved use of Skelaxin under the May 31 labeling.

4. Investigate Elan's activities and cooperate with any allied investigation conducted by the U.S. Federal Trade Commission (FTC) into the anticompetitive activities of Elan that have used the drug approval process to pursue an unlawful monopoly in violation of the antitrust laws.

B. STATEMENT OF GROUNDS

1. Background

a. Skelaxin – An Old Product

Skelaxin was first approved in the early 1960's. According to its approved labeling, it is "indicated as an adjunct to rest, physical therapy, and other measures for the relief of discomfort associated with acute, painful musculoskeletal conditions." Skelaxin's mechanism of action is believed to relate to its sedative properties. No changes to Skelaxin's indications have occurred in, at a minimum, the last two decades.[1] Thus, Skelaxin is not a recent vintage drug product or even one that has been the subject of substantial, successful recent research.

Although Skelaxin has never been protected by Hatch-Waxman non-patent exclusivity or (until very recently, as discussed below) an Orange Book patent, there have never been any generic versions of Skelaxin on the market. Thus, since 1960 Elan has enjoyed a monopoly for this product, which had 2002 sales of approximately $250 million (IMS data).

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[1] Compare 1981 labeling (Exhibit A) with current (August 2002) labeling (Exhibit B).

In 2001, apparently in response to a perceived threat of generic competition, Elan started taking action to protect its longstanding monopoly. Elan's activities, discussed in detail below, led to this petition.

b. Anticompetitive practices by Elan.

In February 2001, Elan submitted general correspondence to its new drug application (NDA) for Skelaxin, which purported to contain laboratory data to support two contentions (Exhibit C). First, Elan argued that metaxalone is poorly soluble in acidic water solutions, such as that which might be found in the stomach after a meal. Second, Elan argued that their "preliminary" data "clearly show that there is not a correlation" between levels of drug released from two tablet formulations in laboratory dissolution studies versus the corresponding levels of drug in a patient's bloodstream. The public health significance of this information, if true, would be that the sponsor of a proposed generic product should establish comparability in blood levels of drug rather than comparability in dissolution under laboratory conditions.

To that end, under relevant statutory authority, FDA generally requires that a generic drug sponsor demonstrate, through laboratory and/or clinical testing, that its product matches that of the reference listed drug in order to obtain authorization for marketing. See 21 U.S.C. § 355(j)(8)(B) and 21 C.F.R. § 320.1(e). In relevant part, FDA generally requires the generic company to obtain data that the blood levels of the generic drug do not vary from a range of 80% to 125% as directly compared to the innovator drug to be considered bioequivalent and therapeutically equivalent. Several types of blood levels are required to match: (1) the highest peak blood level or C_{max} (for maximum concentration); (2) the time point at which peak level is reached or T_{max}; and (3) the total

amount of active ingredient drug that is absorbed or AUC_{inf}.[2] Given patient-to-patient variability, it is not possible to obtain identical levels and, thus, variation within the 80% to 125% range is deemed to be bioequivalence.

In October 2001, Elan submitted a supplement to its Skelaxin NDA containing information comparing blood levels of its product administered while patients were fasting versus drug levels of its product when taken shortly after a standardized high fat meal. Simultaneously, Elan filed a Citizen Petition (Docket No. 01P-0481), requesting that any generic competitor be required to demonstrate in vivo bioequivalence under both fasting and fed conditions for approval (Exhibit D). Elan's data showed that, in the two polar settings of empty stomach versus a recent high fat meal, absorption of metaxalone from Skelaxin tablets into the bloodstream was quite different. The submitted data demonstrated that absorption of metaxalone after a high fat meal was more rapid (earlier T_{max}) and reached a higher earlier peak (higher C_{max}) but that overall absorption or "drug exposure" was not markedly different (fed AUC_{inf} within 80% to 125% of unfed AUC_{inf}). Correspondingly, and implicit in the foregoing changes, the half-life was also found to change.[3] A

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[2] AUC stands for "area under the curve" and represents the "volume" of drug present in the blood over the entire time that drug was present or the total amount that was absorbed from a single dose. AUC_{0-t} is the actually measured active ingredient absorbed during the time period of the study, as study subjects typically will not have blood samples drawn after a set time (t) but will still have drug in their bodies. AUC_{inf} is the calculated total absorption of active ingredient extrapolated from AUC_{0-t} and is the figure used to determine bioequivalence. AUC_{0-t} can vary, obviously, based on when the study blood drawing ends.

[3] The half-life is the time it takes for half the drug to disappear and is calculated based on the time of peak drug level, the maximum drug level, and the persistence of drug in the bloodstream over time. The half-life is therefore dependent on C_{max}, T_{max}, and AUC_{inf}.

notable finding was the substantially greater variation among study subjects in absorption under fed conditions than is typically seen. In sum, under fed conditions, drug was generally absorbed more quickly; however, this quickness was subject to a high degree of person-to-person variability. Notwithstanding this difference, the total amount of drug absorbed did not change.

c. FDA actions on Elan's proposals.

In March 2002, FDA granted, in part, Elan's petition that FDA require an acceptable in vivo bioequivalence study conducted under fed conditions as a condition of approval of any abbreviated new drug application (ANDA) for a generic version of Skelaxin tablets (Exhibit E). FDA did not need to act on Elan's request that ANDA sponsors also be required to submit an acceptable in vivo bioequivalence study under fasting conditions, as FDA had already granted that relief several months earlier.[4] Before those decisions, in vivo bioequivalence studies were not required to support an ANDA approval for a generic version of Skelaxin.

FDA's decisions meant two things. First, a generic sponsor like Eon Labs would have to provide the agency with evidence that the proposed generic product provides the same drug levels in patients' bloodstreams rather than using simpler in vitro dissolution studies. Second, the in vivo data would have to be obtained both for administration after a meal and when taken on an empty stomach.

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[4] FDA did so in its January 30, 2002, letter granting a separate citizen petition submitted by Mutual Pharmaceutical Company (Mutual), another generic drug company.

In granting Elan's petition, FDA cited Elan's study in 42 subjects that showed that there was a marked increase in early drug absorption in patients who had just eaten a high fat meal versus those who had an empty stomach.

On May 31, 2002, the new drug review division responsible for Skelaxin authorized a change in the labeling of Skelaxin (Exhibit F), based on a labeling supplement submitted by Elan.[5] The new labeling stated, in pertinent part:

> In a single center, randomized, two-period crossover study with 42 healthy volunteers (31 males, 11 females), a single 400mg Skelaxin (metaxalone) tablet was administered under both fasted and fed conditions. Under fasted conditions, mean ± S.D. peak plasma metaxalone concentrations (C_{max}) of 983.4 ± 516.9 ng/mL were achieved within 3.3. ± 1.2 hours after dosing (T_{max}). Metaxalone concentrations declined with mean terminal half-life ($t_{½}$) of 9.0 ± 4.8 hours. The mean apparent oral clearance (CL/F) of metaxalone was 53.5 ± 27.1 L/hr. In the same study, the administration of a 400 mg Skelaxin tablet following a standardized high fat mean showed an increase in the mean C_{max} and the area under the curve (AUC_{0-t}) of metaxalone to 177.5% and 123.5%, respectively. The mean T_{max} was also increased to 4.3 ± 2.3 hr, whereas the mean $t_{½}$ was decreased to 2.4 ± 1.2 hr. Given the magnitude of plasma level changes following a high fat meal, Skelaxin should be administered on an empty stomach.

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[5] We find it curious and unusual that FDA's May 31 approval letter has been removed from the agency's website (www.fda.gov/cder/approval/index.htm). The website still lists the May 31 approval, with a "letter posted" date of June 3, 2002. However, the link for this letter leads, without explanation, to the June 20 approval letter, discussed below in the main text.

> The absolute bioavailability of Skelaxin tablets is not known. Metaxalone is metabolized by the liver and excreted in urine as unidentified metabolites. The impact of age, gender, hepatic and renal disease on the pharmacokinetics as Skelaxin tablets has not been demonstrated.

(Emphasis added.)

In a highly unusual move, on June 20, 2002, FDA's new drug review division – without considering any new data – amended the labeling to read as follows (Exhibit G):

> In a single center randomized, two-period crossover study in 42 healthy volunteers (31 males, 11 females), a single 400mg Skelaxin (metaxalone) tablet was administered under both fasted and fed conditions.
>
> Under fasted conditions, mean peak plasma concentrations (C_{max}) of 865.3 ng/mL were achieved within 3.3. ± 1.2 hours after dosing (T_{max}). Metaxalone concentrations declined with mean terminal half-life ($t_{½}$) of 9.0 ± 4.8 hours. The mean apparent oral clearance (CL/F) of metaxalone was 68 ± 34 L/hr.
>
> In the same study, following a standardized high fat meal, food statistically significantly increased the rate of (C_{max}) and extent of absorption ($AUC_{(0-t)}$, AUC_{inf}) of metaxalone from Skelexin tablets. Relative to the fast treatment the observed increases were 177.5%, 123.5% and 115.5%, respectively. The mean T_{max} was also increased to 4.3 ± 2.3 hr, whereas the mean $t_{½}$ was decreased to 2.4 ± 1.2 hr. This decrease in half-life over that seen in the fasted subjects is felt to be due to the more complete absorption of metaxalone in the presence of a meal resulting in a better estimate of half-life. The mean apparent oral clearance (CL/F) of metaxalone was relatively unchanged relative to fasted administration (59 ± 29 L/hr). Although a higher C_{max} and AUC were observed after the administration of Skelexin (metaxalone) with a standardized high fat meal, the clinical relevance of these effects is unknown.

> The absolute bioavailability of Skelaxin tablets is not known. Metaxalone is metabolized by the liver and excreted in the urine as unidentified metabolites. The impact of age, gender, hepatic and renal disease on the pharmacokinetics of Skelaxin tablets has not been demonstrated.

In comparison with the labeling approved on May 31, the agency deleted the following sentence: "Given the magnitude of plasma level changes following a high fat meal, Skelaxin should be administered on an empty stomach." The agency added the following sentences:

> This decrease in half-life over that seen in the fasted subjects is felt to be due to the more complete absorption of metaxalone in the presence of a meal resulting in a better estimate of half-life. The mean apparent oral clearance (CL/F) of metaxalone was relatively unchanged relative to fasted administration (59 ± 29 L/hr). Although a higher C_{max} and AUC were observed after the administration of Skelexin (metaxalone) with a standardized high fat meal, the clinical relevance of these effects is unknown.

The agency also deleted standard deviation values for peak plasma concentrations that would provide physicians with an understanding of the high level of variation among individuals, and added language that increases in C_{max}, AUC_{0-t}, and AUC_{inf} were "statistically significant[]." Finally, the agency made minor data corrections. [6]

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[6] In August 2002, FDA approved Elan's supplemental NDA for an 800 mg strength of Skelaxin. In connection with that approval, FDA approved revised labeling for Skelaxin that includes additional language discussing data from both fed and fasting studies with 800 mg dosing (Exhibit B). This recent addition does not affect the substance of this petition since we are requesting restoration of the pre-June 20 labeling. Additionally, the recent labeling change incorporates the identical deficiencies found in the June 20 labeling.

d. U.S. Patent No. 6,407,128

The '128 patent (Exhibit H) issued on June 18, 2002. The patent has 22 claims which describe and delimit the purportedly novel invention that is awarded protection from competition by the U.S. Patent and Trademark Office. Only three of the claims are "independent" of each other and bear examination. Claim 1 is a method of increasing blood drug levels of metaxalone by administering the product with food.[7] Claim 9 is a method of increasing both the rate (e.g., T_{max}) and extent (e.g., AUC) of blood absorption of metaxalone by administering the product with food. Claim 17 more explicitly claims the invention of increasing both the C_{max} and AUC_{inf} of metaxalone by administering the product with food.

The '128 patent was first listed in the June supplement to the 2002 Orange Book with use code U-189, "enhancement of the bioavailability of the drug substance."

2. FDA Should Grant The Relief Requested By This Petition

a. The May 31 labeling should be restored.

The May 31 labeling for Skelaxin should be restored. That labeling is scientifically sound, while there is no scientific support for the June 20 labeling.

Both versions of labeling are drawn from Elan's pharmacokinetic study conducted in 42 normal, healthy volunteers. In keeping with the nature of the pharmacokinetic study, no clinical data on safety or efficacy were collected or intended to be collected. Yet Elan apparently asked FDA to

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[7] Both before and after the June 20 labeling change, physicians and patients have been practicing this invention for some time, since metaxalone is generally administered 3 to 4 times per day.

go well beyond the limited purpose of a pharmacokinetic study to draw clinical conclusions that are set forth in the June 20 labeling. This was not warranted and is contrary to longstanding FDA practice. In fact, under normal FDA practice, Elan's pharmacokinetic study and request for revision of labeling would have been reviewed only by the Office of Pharmaceutical Science and not by the new drug medical reviewers responsible for Skelaxin labeling, since the study was not designed as a clinical study.

i. The June 20 labeling permits clinicians to draw unsafe conclusions.

Elan's study established that administration of Skelaxin to study subjects after standardized high fat meals results in highly variable, unpredictable, but generally increased drug levels. In Elan's pharmacokinetic study, no inquiry was made into whether the high drug levels seen with administration after meals corresponded to side effects. The clinical significance of these rather substantial changes in the profile of early drug exposure and the variability in peak drug exposure from person-to-person has never been studied and is completely unknown.

Absorption levels of Skelaxin following dosing after other meals or meals more typically ingested by patients with severe acute musculoskeletal pain throughout the day are completely unknown and unstudied. However, based on Elan's data, absorption levels are likely to differ from both standardized high fat meal fed and fasted levels. Without a head-to-head comparison of the differing clinical effects of these two modes of administration and under circumstances of other types of meals, it is clinically unwise, contravenes longstanding FDA policy, and represents a risk to the public health to permit a clinician reading the labeling to draw the erroneous, unsafe conclusion that it would be acceptable for Skelaxin – a drug product with known food-induced changes in

absorption – to be taken with a high fat meal rather than in the fasting state, as properly recognized by FDA in the May 31 labeling. Stating that there are unknown clinical effects does not provide sufficient warning to patients, physicians, or the public about possible risks to individual and public health from the administration of a potent sedative in which overdoses could occur as a result of concomitant administration with food.

In the absence of comparative clinical data, a presumption should be made that higher drug levels result in a higher incidence of untoward events. Clinicians can always increase drug dosage to seek therapeutic efficacy in individual patients but only if absorption and drug levels are kept relatively fixed in relationship to dosage. The only method under which this general rule can be safely applied to metaxalone is for physicians to advise patients to take the drug on an empty stomach. In short, in the absence of any data confirming or denying clinical effect, the only appropriate recommendation to be derived from these data would be to limit metaxalone to administration on an empty stomach.[8]

This was clearly the agency's first and unfettered opinion. The May 31 labeling properly contained the sentence "[g]iven the magnitude of plasma level changes following a high fat meal,

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[8] Typically, in the setting of most chronically or regularly administered drug products (like Skelaxin), total drug exposure or AUC_{inf} (total absorption) is generally more closely related to long term efficacy, whereas acute high levels of exposure (C_{max}) correspond more closely to incidences of toxicity. In this setting, in the absence of any clinical data, the preferred a priori method of drug exposure would be to ensure a consistent AUC_{inf} without risk of high C_{max}. For metaxalone, Elan's studies demonstrated that this circumstance exists only in the setting of administration on an empty stomach.

Skelaxin should be administered on an empty stomach." This sentence should be restored to ensure the safe use of Skelaxin and generic versions of Skelaxin.[9]

ii. The June 20 labeling undercuts the ability of healthcare professionals to assess and understand the high level of inter-individual variability following metaxalone administration.

FDA's June 20 decision to remove standard deviation information on inter-individual variability of absorption after a fed meal limits the ability of clinicians to assess the effects of drug absorption on toxicity or efficacy in individual patients or groups. The standard deviation information showed a high level of variation among individuals, which supports the conclusion that any changes in the average numbers have relatively little clinical significance. These important data inform physicians that some patients might experience toxicity as a result of administration after meals, while other patients would not have such issues. Physicians need to have this information available to assist in managing dosing, because drug levels in a particular person on a particular day may vary significantly depending on such variables as diet.

b. In the alternative, FDA should determine that the May 31 labeling was not withdrawn for safety or effectiveness reasons.

For the reasons discussed above, it should be apparent that the May 31 labeling for Skelaxin was not withdrawn for either safety reasons or effectiveness reasons. Therefore, in the alternative, FDA should make a determination pursuant to 21 C.F.R. § 314.122 that the reference listed drug

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[9] Eon Labs could not properly defend public use of the June 20 labeling were it to obtain approval for its generic product since the company does not have a good faith basis for recommending fed administration in light of current data. A private entity like Eon Labs should not, as a condition of doing business, be forced to purvey false and misleading information and inaccurate renditions of complex scientific data.

Skelaxin, with labeling approved as of May 31, 2002, was not withdrawn for safety or effectiveness reasons. Such a determination would enable generic sponsors to submit ANDAs based on the May 31 labeling.[10]

c. FDA's decision granting Elan's citizen petition should be reversed by deleting the requirement for a bioequivalence study under fed conditions.

For the reasons discussed above, Elan's study that purported to support its October 2001 citizen petition to FDA, which asked FDA to impose a requirement for in vivo bioequivalence studies under both fasting and fed conditions for any generic versions of Skelaxin tablets, is substantially flawed from the scientific perspective. Properly interpreted, Elan's data established that Skelaxin should be administered only on an empty stomach, as set forth in the Skelaxin labeling approved by FDA on May 31, 2002. Accordingly, the labeling for Skelaxin should expressly recommend that it be administered only on an empty stomach.

For such a drug product, there is no scientific, regulatory, or legal reason to support a requirement for a bioequivalence study conducted under fed conditions. A generic competitor

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[10] As the indications for use of Skelaxin (with the June 20 labeling) and a generic product (with the May 31 labeling) would be identical, the generic product should be rated "AB" in the Orange Book in comparison with Skelaxin. The approval of a generic product with different labeling than the innovator product's labeling and the resulting substitution of the generic product for the innovator product under state pharmacy laws does not undermine the innovator firm's rights under the Hatch-Waxman Amendments. See Bristol-Myers Squibb Co. v. Shalala, 91 F.3d 1493, 1500 (D.C. Cir. 1996).

should not be required to submit data to establish the bioequivalence of its product using a method of administration that is expressly not recommended.[11]

Therefore, FDA should reverse its March 2002 decision granting Elan's citizen petition, and delete the requirement for a bioequivalence study conducted under fed conditions to support the approval for any generic versions of Skelaxin.

d. FDA should delist the '128 patent as it does not claim a use of Skelaxin as properly labeled.

Assuming that FDA grants our request that the May 31 labeling be restored, it follows that the '128 patent should be delisted as it no longer would claim an approved use of Skelaxin. Under the May 31 labeling, administration of Skelaxin under fed conditions is expressly not recommended. However, as discussed above, the '128 patent only claims the use of Skelaxin under fed conditions. If the May 31 labeling of Skelaxin is restored, the '128 patent plainly does not claim an approved use

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[11] This conclusion is also supported by the high rate of inter-individual variability in pharmacokinetic values in the fed state. As noted before, the variation in drug levels between fed and unfed are based on characteristics of the active ingredient and not on any company's formulation. Stated differently, variation due to drug formulation between manufacturers is trivial in comparison to variation due to unknown individual factors and due to the active ingredient itself. In this setting, FDA should not require demonstration of bioequivalence of formulations in the fed state since the only way to acquire such data is by purposefully designing a poor clinical study rather than by assuring that the generic formulation dissolves and is absorbed the same way as the innovator's product. Thus, achieving bioequivalence functionally means identifying a duplicate patient population that has the same absorption characteristics of the subject population used by Elan rather than duplicating the chemically-determined dissolution or absorbance characteristics. This turns the principles of generic substitution upside down: rather than showing the drug formulations can be safely interchanged, the generic competitor would have to show that patient populations can be safely interchanged to achieve bioequivalence. The obvious and better solution is to limit administration or data generation to settings which do not implicate drug-related inter-individual variability and where such variability does not overwhelm any trivial chemical differences.

of Skelaxin as required by 21 C.F.R. § 314.53(b). Hence, the patent is not eligible for Orange Book listing and should be delisted by FDA. [12]

e. The actions of Elan are potentially improper and require investigation.

For the reasons discussed above, Eon Labs believes there is no scientific basis for the labeling approved on June 20. Rather, the underlying rationale of the revised labeling approved on June 20 appears to be preservation of Elan's monopoly. Eon Labs is wholly unaware of the nature and extent of communications between Elan and FDA between May 31 and June 20, when FDA took the unusual step of approving revised labeling despite the absence of new study data. Nonetheless, we believe that an FDA investigation is warranted to ensure that no improper activities took place.[13]

Eon Labs is concerned that Elan's use of the FDA drug approval process to perpetuate its Skelaxin monopoly and defer generic competition may be in violation of federal antitrust and unfair competition laws. Accordingly, contemporaneous with the submission of this petition, Eon Labs is

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[12] We acknowledge that some courts have recently concluded that FDA has a purely ministerial role in the listing of patents in the Orange Book. E.g., aaiPharma, Inc. v. Thompson, 296 F.3d 227, 238-39 (4th Cir. 2002); Watson Pharm., Inc. v. Henney, 194 F. Supp. 2d 442, 445-46 (D. Md. 2001). We respectfully submit that these cases are incorrectly decided, and note that the issue is currently pending before the U.S. Court of Appeals for the Federal Circuit – the appellate court with jurisdiction over patent matters – in Apotex, Inc. v. Thompson, No. 02-1295. Oral argument in that case is scheduled for February 4, 2003.

[13] We stress that we have no evidence other than the outcome, and the unusual course and stated basis for the outcome, to suspect improper activities.

asking the FTC to investigate potential violation of any federal laws under its jurisdiction. We request that FDA cooperate with any such investigation.

3. Conclusion

For the reasons stated, there is no scientific rationale supporting Elan's June 20 labeling, with its attendant risk to the public. Continuation of the June 20 labeling would also support anticompetitive and monopolistic practices by Elan. Thus, FDA should restore the May 31 labeling of Skelaxin. In the alternative, FDA should determine that the May 31 labeling was not withdrawn for safety or effectiveness reasons. FDA should also reverse its grant of Elan's citizen petition, remove the requirement for fed studies to establish bioequivalence to Skelaxin, delist the '128 patent from the FDA Orange Book, and investigate Elan for potentially improper practices. Finally, FDA should cooperate with any FTC investigation into Elan's monopolistic practices in potential violation of the antitrust laws.

In closing, we note that the relief requested by this petition is necessary to implement one of the goals of the Hatch-Waxman Amendments of 1984: "get generic drugs into the hands of patients at reasonable prices – fast." In Re: Barr Laboratories, Inc., 930 F.2d 72, 74 (D.C. Cir. 1991). Elan's anticompetitive activities are having the exact opposite result and should not be countenanced by FDA.

C. ENVIRONMENTAL IMPACT

This petition is entitled to a categorical exclusion under 21 C.F.R. § 25.30 and § 25.31.

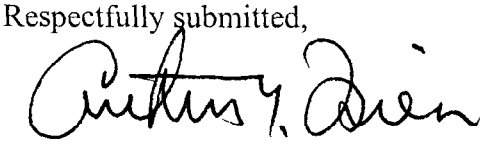
D. ECONOMIC IMPACT

Information regarding economic impact will be submitted on request.

CERTIFICATION

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

Respectfully submitted,



Arthur Y. Tsien
Jur T. Strobos, M.D.
Counsel to Eon Labs, Inc.

Exhibits

A	1981 Skelaxin labeling
B	August 2002 Skelaxin labeling
C	Elan letter to FDA, February 27, 2001
D	Elan citizen petition, October 16, 2001
E	FDA letter granting, in part, Elan's petition, March 21, 2002
F	FDA letter to Elan, May 31, 2002
G	FDA letter to Elan, June 20, 2002
H	U.S. Patent No. 6,407,128