



Memorandum

DEC 17 2002

Date:

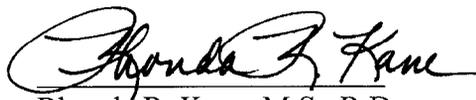
From: Consumer Safety Officer, Division of Standards and Labeling Regulations, Office of Nutritional Products, Labeling and Dietary Supplements, HFS-821

Subject: 75-Day Premarket Notification of New Dietary Ingredients

To: Dockets Management Branch, HFA-305

Subject of the Notification:	El Jack
Firm:	Herbal Powers, Inc.
Date Received by FDA:	March 18, 2002
90-Day Date:	June 16, 2002

In accordance with the requirements of section 413(a) of the Federal Food, Drug, and Cosmetic Act, the attached 75-day premarket notification and related correspondence for the aforementioned substance should be placed on public display in docket number 95S-0316 as soon possible since it is past the 90-day date. Thank you for your assistance.


Rhonda R. Kane, M.S., R.D.

Attachments

95S-0316

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Annie Eng
Herbal Powers, Inc.
2138 West Jackson Suite #2
Chicago, Illinois 60612

Dear Ms. Eng:

This letter is in response to two separate notifications you submitted to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 350b(a)(2). FDA received and filed the notifications on March 18, 2002. Each notification concerns a different botanical that you assert is a new dietary ingredient. Proposed product names and the Latin binomial names for the ingredients are listed below as stated in your notifications, with the exception that the species names are not capitalized:

- Lamila capsule 270 mg [*Labisia pumila* F. Vill]
- El Jack capsule 290 mg [*Eurycoma longifolia* Jack]

Earlier, you submitted notifications for El Jack and Lamila that were dated January 28, 2002, and were received and filed by FDA on February 26, 2002.

Mr. Gary Coody on my staff contacted you by phone to request clarification regarding the names for El Jack and Lamila and you responded with the authors' names as indicated above. The author designation, F. Vill, you submitted for the Latin binomial name *Labisia pumila* is incorrect. The correct Latin binomial name and author designation for this plant is *Labisia pumila* Benth. & Hook. f. For the purposes of this letter, *Labisia pumila* will be used to refer to the plant source of Lamila.

Your notification states that Lamila will contain 270 mg per capsule of powdered whole plant of *Labisia pumila*. The proposed label will instruct consumers to take 2 capsules twice daily one hour before meals. The indicated conditions of use and the proposed text of the label submitted for Lamila include the following statements: may help alleviate fatigue; soothe menopausal symptoms; harmonize female reproductive system and menstrual cycle; enhance women's overall vitality and youthfulness; strengthen uterus; firm breast; enhance overall postpartum recovery; and tighten pelvic muscle after delivery. The proposed label also includes cautionary statements for potential consumers to consult a medical professional if they are taking a prescription medicine, are pregnant or nursing a baby, and to immediately seek the advise of a healthcare professional in case of accidental ingestion or overdose.

Your other notification states that El Jack will contain 290 mg per capsule of powdered root of *Eurycoma Longifolia* Jack with label instructions to take 2 capsules daily. The indicated conditions of use for El Jack include the following statements: may help increase the efficiency of the healing system by supporting a healthy immune system; improve overall energy levels; reduce fatigue and exhaustion; enhance overall male

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sexual vitality; improve appetite and digestion; and tone skin and muscle. The proposed label also includes cautionary statements for potential consumers to consult a medical professional if they are taking a prescription medicine, are pregnant or nursing a baby, and to immediately seek the advise of a healthcare professional in case of accidental ingestion or overdosage.

The statement "help increase the efficiency of the healing system" may cause El Jack to be represented as a drug. Under 21 U.S.C. 321(g)(1)(B), a drug is defined as an article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals. Therefore, if you intend to make claims of this nature and you want El Jack to be evaluated for its use in the treatment of a disease, you should contact FDA's Center for Drug Evaluation and Research, Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

The law at 21 U.S.C. 350b(a)(2) requires that a manufacturer or distributor submit certain information to FDA at least 75 days before a new dietary ingredient or a dietary supplement containing it is introduced or delivered for introduction into interstate commerce. This information must include the basis on which the manufacturer or distributor has concluded that the new dietary ingredient or a dietary supplement containing it will reasonably be expected to be safe. FDA reviews this information to determine whether it provides an adequate basis for such a conclusion. Under 21 U.S.C 350b(a)(2), there must be a history of use or other evidence of safety establishing that the dietary ingredient, when used under the conditions recommended or suggested in the product's labeling, will reasonably be expected to be safe. If this requirement is not met, the new dietary ingredient or dietary supplement containing it is deemed to be adulterated under 21 U.S.C. 342(f)(1)(B), because there is inadequate information to provide reasonable assurance that the new dietary ingredient does not present a significant or unreasonable risk of illness or injury.

FDA carefully considered the information in your notifications. We have significant concerns about the basis upon which you concluded that a dietary supplement containing *Eurycoma longifolia* or *Labisia pumila* is reasonably expected to be safe when used as recommended or suggested in the products' labeling. These concerns for each ingredient are discussed below.

El Jack

The history of use information provided in your notification states that *Eurycoma longifolia* is indigenous to Southeast Asia and Indo-China and has been used by the locals in folk medicine as a febrifuge and a remedy for "intermittent fevers." It also refers to *Eurycoma longifolia* as a "tree of 100 remedies." This history of use information lacks details on the amount, frequency and duration of use for the botanical and whether the plant parts or preparation used are the same as what you intend to market in El Jack. Without these details, it is not possible for FDA to determine how this information relates to your product.

Your notification also includes a photocopy and translation of a registration held by Tomrich Marketing with the Drug Control Authority of Malaysia for "E.L. Jack Capsule"

for the following approved indication: "traditionally used for improving energy, reduce body fatigue and enhance overall performance". You assert in your notification, but without supporting documentation, that over "20 million capsules of E.L. Jack Capsules have been sold in Asia since 1997 and that there have been no serious side effects or drug interactions reported to date when used as directed." FDA is not aware of any systematic collection of data related to adverse effects occurring in individuals using E.L. Jack capsules. Further, absence of adverse event reports does not necessarily mean a particular product or ingredient has not been or is not likely to be associated with an adverse event, nor does it provide adequate evidence of safety for El Jack.

Your notification also includes copies of what appear to be promotional materials and newspaper clippings from unidentified sources intermixed with research publications of *invitro* and *invivo* animal studies. Sources are not provided for several of the research publications. Medicinal benefits for *Eurycoma longifolia* stated in the materials include the following: aphrodisiac, androgenic, antiviral, antimalarial, antipyretic, antihistaminic, antiulcer, antianxiety, anticancer tumor, antihypertensive, antidysentery, and others. None of the papers directly assess safety nor do they provide any safety data for exposure of *Eurycoma longifolia* in humans. Furthermore, since the relationship between *invitro*, animal and human exposure is unknown, the applicability of these results to humans is unclear. Of additional concern is the possibility that *Eurycoma longifolia* may increase testosterone levels, as suggested by the Kwan *et. al.* paper. If this were confirmed in humans, it could pose a safety risk in men with prostate cancer or other medical conditions. A Certificate of Analysis included in your notification for the Malaysian *Eurycoma longifolia* capsule drug product indicates that it was assayed for glucocorticosteroids, but not for testosterone or any other androgenic compounds. In summary, your notification has provided no data or publications that can be used to assess the safety of El Jack capsule when used as you direct.

Lamila

Your notification states that *Labisia pumila* is indigenous to Southeast Asia and has been used by the local women for vitality and restoring youthfulness. This history of use information lacks details on the amount, frequency and duration of use for the botanical and whether the plant parts and preparation used are the same as what you intend to market in Lamila. Without these details, it is not possible for FDA to determine how this information relates to your product.

Your notification also includes a photocopy and translation of a registration held by Tomrich Marketing with the Drug Control Authority of Malaysia for "Labisia pumila capsules" for the following approved indication: "traditionally used for improving energy and women's health." You assert in your notification, but without supporting documentation, that over 2 million capsules of *Labisia pumila* capsules have been sold in Asia since 1999 and that there have been no serious side effects or drug interactions reported to date when used as directed. FDA is not aware of any systematic collection of data related to adverse effects occurring in individuals using *Labisia pumila* capsules. Further, absence of adverse event reports does not necessarily mean a particular product or ingredient has not been or is not likely to be associated with an adverse event, nor does it provide adequate evidence of safety for Lamila.

Also attached to your notification are what appear to be promotional materials and other articles from unidentified sources. The materials include statements of medicinal uses for *Labisia pumila* that include but are not limited to the following: treat dysmenorrhea, rheumatism, gonorrhea, and dysentery; support healthy vaginal flora to prevent irritation and infections; speed up healing of the womb and birth canal after childbirth; strengthen the uterus and bladder from slipping out of place; and alleviate flatulence. The articles state that *Labisia pumila* contains phytoestrogens. However, the notification contains only one abstract by Jamal *et. al.* that mentions the presence of weak phytoestrogens in *Labisia pumil*, but no data is provided. A Certificate of Analysis for the *Labisia pumila* drug product by Tomrich Marketing indicates that assays were performed for glucocosteroids but not for estrogens or other compounds known to have estrogenic activity. In summary, there is no information in the materials submitted in your notification to assess the safety of *Labisia pumila* when used as you direct.

Conclusions

For the reasons discussed above, the information in your notification on Lamila does not provide an adequate basis to conclude that it will reasonably be expected to be safe when used under the conditions recommended or suggested in the product's labeling. Also as stated above, because the information in your submission indicates that El Jack is represented as a drug and not a dietary supplement, it would be subject to regulation as a drug. Notwithstanding, even if it could be argued that El Jack is a dietary supplement, the information in your notification does not provide an adequate basis to conclude that it will reasonably be expected to be safe when used under the conditions recommended or suggested in the product's labeling. Therefore, Lamila and El Jack may be adulterated under 21 U.S.C. 342(f)(1)(B) as dietary supplements that contain the new dietary ingredients *Labisia pumila* or *Eurycoma longifolia* for which there is inadequate information to provide reasonable assurance that such ingredients do not present a significant or unreasonable risk of illness or injury. Introduction of such products into interstate commerce is prohibited under 21 U.S.C. 331(a) and (v).

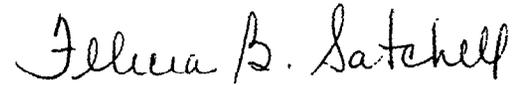
Your notifications will be kept confidential for 90 days after the filing date. After June 16, 2002, the two notifications will be placed on public display at FDA's Docket Management Branch in docket number 95S-0316. However, any trade secret or otherwise confidential commercial information in the notifications will not be disclosed to the public. Prior to June 16, 2002, you may wish to identify in writing specifically what information you

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believe is proprietary in each of your notifications for FDA's consideration. Nevertheless, our Center's Freedom of Information Officer has the authority to make the final decision about what information in the notifications should be redacted before they are posted at Dockets.

Please contact us at (301) 436-2371, if you have questions concerning this matter.

Sincerely yours,



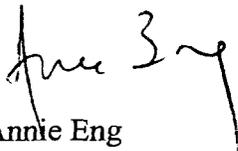
Felicia B. Satchell
Director
Division of Standards
and Labeling Regulations
Office of Nutritional Products, Labeling
and Dietary Supplements

Gary Coody
FDA
5100 Paintbranch Pkwy
HSF 805
College Park, MD 20740-3835

Dear Gary,

I have enclosed 4 copies of new letter for *Eurycoma Longifolia* and 4 copies of new letter for *Labisia Pumila*. These new letters contain the latin author name for each botanical. Please disregard the old letters. Thank you.

Sincerely,



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