PROPOSED REGULATION OF THE COMMISSIONER OF

FOOD AND DRUGS

LCB File No. R051-97

August 6, 1997

EXPLANATION – Matter in *italics* is new; matter in brackets **[ ]** is material to be omitted.

AUTHORITY: §§ 1 and 2, NRS 585.210 and 585.495.

Section 1. Chapter 585 of NAC is hereby amended by adding thereto a new section to read as follows:

1. The board will consider an application for a license required pursuant to NAC 585.220 to manufacture, prepare or compound amygdalin (laetrile) or procaine hydrochloride with preservatives and stabilizers, and the written recommendation of the commissioner regarding the application, at a public hearing held:

(a) At the time and place of the next regularly scheduled meeting of the board;

(b) At the next meeting of the board that is scheduled in Carson City, Reno or Las Vegas, whichever city is requested by the applicant; or

(c) As soon as the schedule of the board permits.

2. The board is not required to follow the written recommendation of the commissioner regarding the application.

3. At the public hearing, the applicant and the commissioner may address the board and answer any questions of the board regarding the application. At the conclusion of the presentations by the applicant and the commissioner, the board will render a decision granting or denying the application. The board will notify the applicant in writing of its findings of fact, conclusions of law and decision regarding the application as soon as practicable after the date of the hearing.

Sec. 2. NAC 585.220 is hereby amended to read as follows:

585.220 1. No natural person, partnership, association, corporation or other business organization may manufacture, prepare or compound amygdalin (laetrile) or procaine hydrochloride with preservatives and stabilizers without a license from the **[**state board of health.**]** *board.*

2. The **[**state board of health**]** *board* will not grant a license to manufacture *, prepare or compound* amygdalin or procaine hydrochloride unless the applicant has satisfied the commissioner that the applicant:

(a) Is a person of good character, honesty and integrity;

(b) Is a person whose background, reputation and associations will not result in adverse publicity for the State of Nevada and its drug manufacturing industry; and

(c) Has adequate business competence and experience for the role or position for which application is made.

3. The **[**state board of health**]** *board* will not grant a license to manufacture *, prepare or compound* amygdalin or procaine hydrochloride unless the applicant has satisfied the

commissioner that the proposed financing of the entire operation will be adequate for the nature of the operation and will be obtained from a suitable source. The commissioner will determine the suitability of the source in accordance with the standards **[**enumerated**]** *set forth* in subsection 2.

4. **[**No natural person, partnership, association, corporation or other business organization may manufacture, prepare or compound any drug other than amygdalin or procaine hydrochloride without a license from the commissioner.

5. The commissioner**]** *The board* will not issue a license to manufacture **[**a drug other than**]** *, prepare or compound* amygdalin or procaine hydrochloride unless the **[**applicant has satisfied the commissioner that the applicant:

(a) Will construct or has constructed a plant in accordance with a set of plans approved by the commissioner;

(b) Has the competence to manufacture the drug; and

(c) Has the business competence and adequate experience for performing in the role or position for which the application is made.**]** *commissioner has examined and approved:*

(a) The formula for the drug, including, without limitation, all components of the drug, to ensure compliance with NAC 585.200 and 585.210; and

(b) The procedures to be used in processing the drug to ensure that the formula is not altered by such procedures.