CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:83607

ENVIRONMENTAL ASSESSMENT AND/OR FONSI

ENVIRONMENTAL IMPACT ANALYSIS REPORT

Date: APR 11 1973

Name of applicant: Richlyn Laboratories, Inc.

Address: Castor & Kensington Avenues, Philadelphia, Pennsylvania 19124

1. Describe the proposed action: (A)Manufacture a/o distribution of QA-approved subject drug. (B)Destruction(comminution, wetting), containment (sealed,polyethylene-lined fiber drums) and disposal (delivery by state-licensed contractor to state-licensed sanitary landfill) of QA-rejected waste, recalled, or banned subject drug.

2. Discuss the probable impact of the action on the environment (including primary and secondary consequences): (A.1.)Prevention and treatment of disease; some adverse reactions to drug. (A.2.)Excretion of bio-diluted drug into raw sewage. (B.1.)Topological improvement of landfill site. (B.2.)Slow, eventual dissemination of rejected drug into land adjoining landfill site.

3. Discuss the probable adverse environmental effects which cannot be avoided: (A.1.)Adverse reactions in some users. (A.2.)Drug residue excretion into environment. (B)Long-term dissemination of drug rejects into land adjoining landfill site.

4. Evaluate alternatives to the proposed action: (A) Unavailability of needed drug. (B)Combustion (heat and air pollution); dilution and drainage to sewage or open water (prohibited) or to holding tanks (impractical); deep space shot (not yet feasible); degradation to ecology-acceptable moieties (not yet practical).

5. Describe the relationship between local short-term uses of the environment with respect to the proposed action and the maintenance and enhancement of long-term productivity: (A)Predominantly beneficial. (B)Current state-of-art capability analysis indicates that both short- and long-term considerations are best served by approval of the proposed action.

6. Describe any irreversible and irretrievable commitment of resources which would be involved in the proposed action should it be implemented: (A)Excreted drug will be wasted. (B)The drug rejects and their containment polyethylene-lined drums will be wasted re re-use. The landfill site is topologically improved.

7. Discuss the objections raised by other agencies, organizations, or individuals which are known to the applicant: (A)Therapeutic nihilists oppose drug use. (B) Ecologists generally object to all known means of waste handling. We feel our proposal represents a minimally objectionable means to a vital end.

8. If proposed action should be taken prior to 90 days from the circulation of a draft environmental impact statement or 30 days from the filing of a final environmental impact statement explain why: (A)Delay unduly denies public access to currently needed therapy. (B)Delay results in waste stockpiling in a drug manufacturing facility. This is not compatible with current good Manufacturing Practices per 21CFR§133.

9. Analyze whether the benefit to the public of the proposed action will outweigh the action's potential risks to the environment: Based on the above considerations, we submit that the proposal's actual benefits to the public far outweigh its related potential risks to the environment. This applies to short- and long-term evaluations.

APR 11 1973
(Date)

(Signature of responsible official)

(VICE PRESIDENT)