

Code of Federal Regulations]

[Title 21, Volume 7]

[Revised as of April 1, 2001]

From the U.S. Government Printing Office via GPO Access

[CITE: 21CFR601.20]

[Page 26-27]

TITLE 21--FOOD AND DRUGS

DEPARTMENT OF HEALTH AND HUMAN SERVICES--(Continued)

PART 601--LICENSING--Table of Contents

Subpart C--Biologics Licensing

Sec. 601.20 Biologics licenses; issuance and conditions.

(a) Examination--compliance with requirements. A biologics license application shall be approved only upon examination of the product and upon a determination that the product complies with the standards established in the biologics license application and the requirements prescribed in the regulations in this chapter including but not limited to the good manufacturing practice requirements set forth in parts 210, 211, 600, 606, and 820 of this chapter.

(b) Availability of product. No biologics license shall be issued unless:

(1) The product intended for introduction into interstate commerce is available for examination, and

(2) Such product is available for inspection during all phases of manufacture.

(c) Manufacturing process--impairment of assurances. No product shall be licensed if any part of the process of or relating to the manufacture of such product, in the judgment of the Director, Center for Biologics Evaluation and Research, would impair the assurances of continued safety, purity, and potency as provided by the regulations contained in this chapter.

(d) Inspection--compliance with requirements. A biologics license shall be issued or a biologics license application approved only after inspection of the establishment(s) listed in the biologics license application and upon a determination that the establishment(s) complies with the standards established in the biologics license application and the requirements prescribed in applicable regulations.

[[Page 27]]

(e) One biologics license to cover all locations. One biologics license shall be issued to cover all locations meeting the establishment standards identified in the approved biologics license application and each location shall be subject to inspection by FDA officials.

[64 FR 56451, Oct. 20, 1999]