

12362 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

2. Information on the dosage forms and the quantity of active ingredients in each such dosage form made or supplied by such firms.
3. Information possessed by the FDA on product stability or instability of each product.
4. Information on whether each manufacturer or supplier provides expiration dating on each product and the stability of the drug during the period of the expiration dating, if known.
5. Whether bioavailability data have been gathered by each manufacturer and the nature of such data.
6. Whether the manufacturer has successfully processed an NDA or an abbreviated NDA for the drug being considered.
7. If bioavailability tests have not been conducted, a statement of the authority for presumed bioequivalence.
8. Statements regarding the presence or absence of any information on therapeutic inequivalence.
9. The date and general findings of the last factory inspection conducted by FDA on the facilities utilized by each manufacturer in the production of the specific drug or class of drugs.
10. Identification of those compendial or reference standards on which the drug is evaluated.
11. Information on pending changes in pertinent compendial standards.
12. Information on the market availability on a national basis of each individual firm's drug products.