# Foreword

The worldwide pharmaceutical industry has a dollar sales volume greater than $100 billion with a number of individual drugs boasting sales volumes of over $100 million each. Indeed some drugs have been called "blockbuster drugs"—those generating at least $300 million in new revenues each year. The profit margins in drug manufacture are higher than the rest of the chemical industry and, of course, research expenditures are huge in order to maintain position and develop new drugs in this highly competitive industry.

The present-day drug industry is one of rapid change.

Patents on current best-selling drugs are expiring. It has been estimated that the top 100 products in the marketplace will all come off patent (that is, the basic patents will expire) in the period between 1973 and 1990.

As patents expire, exclusivity of producing a trade-named product will pass and competitive-versions of the basic drug will be marketed under generic names (or other new trade names) by new manufacturers. It has been estimated that 40% of the drugs on the market in 1990 will be generic drugs.

New products will come on the market as

New products are developed through research.

Products now marketed in Europe and Asia attain approved status by the U.S. Food and Drug Administration (FDA) and enter the huge and lucrative American market.

Information on patented processes offers a number of commercial opportunities:

(1) The patent expiration date (in the U.S. usually 17 years after the patent issuance date cited) offers the opportunity to duplicate and practice the patented process without legal conflict after expiration.

(2) The statement of ownership of the patents affords the opportunity to license the patent in question from the patent holder.

(3) The definition of the patented process offers the opportunity to an innovative chemist to develop a process which bypasses the original patent claims and offers a new legally clear route to an economically attractive product.

This encyclopedic work gives details for the manufacture of 1295 pharmaceuticals, now being marketed as trade-named products somewhere in the world. The pertinent process information has been obtained from examples given in the pertinent patent literature (usually U.S. patents and sometimes British patents).

In addition to the patent-derived process information, references are also cited under each drug's entry to major pharmaceutical reference works where additional information can be obtained on synthesis methods and the pharmacology of the individual products.

This work is presented in two volumes. The arrangement within the books is alphabetic by generic name. The table of contents appears at the beginning of Volume 1. There is also an index by trade names used in many of the countries in the world. Another index lists the raw materials used in the manufacture of the various drugs, an index which should be commercially valuable to suppliers of chemical raw materials to the pharmaceutical industry. These indexes appear at the end of Volume 2.

These volumes provide a handy first reference both to manufacturing process and also to other reference sources where additional details on the product may be found.

This handbook should be useful as an initial point of access to the commercial pharmaceutical literature. It can be consulted as a master source before using computerized retrieval even if computer data on the pertinent literature are readily available.

This work summarizes practical information available from the work of hundreds of pharmaceutical research laboratories and of thousands of chemists in those laboratories in developing thousands of commercial products.

Finally, it is hoped that these books will offer a sort of blueprint for entry into profitable generic drug manufacture. Companies not now in the drug business but with some expertise in fermentation processes and/or chemical synthesis may be able to add a few technical people and make a relatively small investment to get themselves on the first rung of the ladder to being pharmaceutical producers. Study of available technology, patent expiration dates and existing markets for particular trade-named drugs may well lead to routes to promising new ventures.