BIBLIOGRAPHY OF PHARMACEUTICAL RESEARCH

Compiled by A. G. DuMez, Reporter on the Progress of Pharmacy.

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ACCURACY OF HYPODERMIC TABLETS.

The degree of accuracy with which hypodermic tablets should comply with their declared compositions is outlined in a ruling under the Federal Food and Drugs Act issued October 22nd by the Bureau of Chemistry, United States Department of Agriculture. The text of the ruling follows:

Within the last few years the Bureau of Chemistry, in the enforcement of the Food and Drugs Act, has given particular attention to medicinal tablets, especially the more commonly used hypodermic tablets. The data thus collected show that most tablets on the market comply reasonably well with the compositions declared. A material number, however, were found to vary from the stated compositions by amounts in excess of what should be expected under properly controlled conditions of manufacture.

These preparations are of prime importance medicinally. They are manufactured from physiologically potent substances and constitute the chief dependence of the physician in emergencies. The physical characteristics of a hypodermic tablet usually furnish no information as to its quantitative composition. Physicians, druggists, and patients must rely upon the label. Serious consequences may follow any misstatement.

The Bureau of Chemistry will regard as adulterated or misbranded, or both, those hypodermic tablets which fail to comply with declared compositions to an extent greater than occurs in such tablets manufactured under properly controlled processes. In ascertaining the degree of accuracy practicable careful consideration will be given to the conclusions of committees representing the drug manufacturing industry which have studied this question thoroughly and have presented a comprehensive report to the Bureau of Chemistry. These committees have suggested the maximum variations, either above or below the labeled or claimed amounts (including all tolerances), which in their opinion should be permitted in tablets manufactured under properly controlled processes. They are as follows: