



**FIGURE 8.2**

An FDA analyst certifying penicillin samples. (From FDA. With permission.)

- Specific authority was provided for factory inspections.
- Food standards were required to be set up when needed “to promote honesty and fair dealing in the interest of consumers.”
- Federal court injunctions against violations were added to the previous legal remedies of product seizures and criminal prosecutions.<sup>9</sup>

### ***The Preventive Amendments***

During my introduction, I mentioned the correlation between longevity and the advancement of pharmaceutical drugs from 1930 through the present time. Wallace Janssen cites the FDDCA of 1938, World War II and wartime demands, and the development of new “wonder drugs,” especially antibiotics, for setting the table for what he calls the preventative amendments. These new wonder drugs were made subject to FDA testing beginning with insulin in 1941, followed by amendments addressing penicillin and other antibiotics beginning in 1945 (Figure 8.2).<sup>10</sup>

### ***The 1962 Kefauver–Harris Amendment***

The 1962 Kefauver–Harris Amendment was an amendment to the FDDCA of 1938. This was an important act because it required drug manufacturers