

labeling is set forth in Title 21, Part 201, of the Code of Federal Regulations (CFR) (21 CFR §201.10). An excerpt from 21 CFR §201.10 discloses that (22):

If the drug is in tablet or capsule form or other unit dosage form, any statement of the quantity of an ingredient contained therein shall express the quantity of such ingredient in each such unit . . . [s]uch statements shall be in terms that are informative to licensed practitioners, in the case of a prescription drug, and to the layman, in the case of a nonprescription drug.

Other requirements from 21 CFR §201.56, include (23):

- (1) The labeling must contain a summary of the essential scientific information needed for the safe and effective use of the drug.
- (2) The labeling must be informative and accurate and neither promotional in tone nor false or misleading in any particular. The labeling must be updated when new information becomes available that causes the labeling to become inaccurate, false, or misleading.
- (3) The labeling must be based whenever possible on data derived from human experience. No

implied claims or suggestions of drug use may be made if there is inadequate evidence of safety or a lack of substantial evidence of effectiveness. Conclusions based on animal data but necessary for safe and effective use of the drug in humans must be identified as such and included with human data in the appropriate section of the labeling.

## b. Classes of Drugs

Drugs can be classed by the *Anatomical Therapeutic Chemical* (ATC) system (24,25,26,27,28). This system is based on the assumption that compounds with similar physical and chemical properties exhibit similar biological activities (29). Lin et al. (30) describe the utility of the ATC system, and also identify a number of databases that list drugs, their associated adverse events, and drug targets. One such database is Drugbank, available from the University of Alberta. Drugdex, provided by Thomson Reuters, is another database on dosage, pharmacokinetics, indications, and ADRs. The ATC system, as well as the listed databases, can aid in drafting package inserts.

<sup>22</sup>21 Code of Federal Regulations 201.10 (April 1, 2010 version).

<sup>23</sup>21 Code of Federal Regulations 201.56 (April 1, 2010 version).

<sup>24</sup>Takarabe M, Shigemizu D, Kotera M, Goto S, Kanehisa M. Characterization and classification of adverse drug interactions. *Genome Inform.* 2010;22:167–75.

<sup>25</sup>Imming P, Sinning C, Meyer A. Drugs, their targets and the nature and number of drug targets. *Nat. Rev. Drug Discov.* 2006;5:821–84.

<sup>26</sup>Bender A, Scheiber J, Glick M, et al. Analysis of pharmacology data and the prediction of adverse drug reactions and off-target effects from chemical structure. *ChemMedChem.* 2007;2:861–73.

<sup>27</sup>Imming P, Buss T, Dailey LA, et al. A classification of drug substances according to their mechanism of action. *Pharmazie.* 2004;59:579–89.

<sup>28</sup>Gurulingappa H, Kolárik C, Hofmann-Apitius M, Fluck J. Concept-based semi-automatic classification of drugs. *J. Chem. Inf. Model* 2009;49:1986–92.

<sup>29</sup>Dunkel M, Günther S, Ahmed J, Wittig B, Preissner R. SuperPred: drug classification and target prediction. *Nucleic Acids Res.* 2008;36:W55–W59.

<sup>30</sup>Lin SF, Xiao KT, Huang YT, Chiu CC, Soo VW. Analysis of adverse drug reactions using drug and drug target interactions and graph-based methods. *Artif. Intell. Med.* 2010;48:161–6.