

Draft Possible Recommendations

1. FDA should adopt a single standard document for communicating essential information about pharmaceuticals, which would replace the current set (PPI, CMI, and MG), through an appropriate consultative process.
2. That standard document should include quantitative summaries of risks and benefits, along with use and precaution information.
3. FDA should adopt the Drug Facts Box format as its standard. It should engage in a process for creating a standard for elaborating information. This adoption should be supported by a rigorous evaluation process, building on existing research.
4. FDA should rely on its existing review processes to derive the authoritative information that the standard document requires, including pharmaceutical company submissions and expert panel summaries. It should create a process for ensuring up-to-date information on all drugs.
5. FDA-approved and required communications should be subject to rigorous empirical evaluation of their effectiveness.
6. FDA should establish performance standards for the effectiveness of the standard document(s), defined in terms of individuals who have received it.
7. FDA should conduct a systems analysis of the dissemination processes by which the standard document(s) reach consumers at times relevant to their decision making about a product's adoption and use.
8. FDA should identify populations for which the standard document or the dissemination system is inadequate. It should address their needs, where that is within its capabilities, and partner with other organizations, where it is not.
9. FDA should continue to strengthen its practice of relying on the best available social and behavioral science for designing and evaluating communications, including research on textual, numerical, and visual displays. It should foster research relevant to improving the effectiveness and dissemination of its standard document(s). It should include analytical research for identifying the information most critical to the decision making of target audiences.