26. How should individuals/parents have access to registry information on themselves/their children?
27. Should data maintained in a state and community-based immunization registry be considered public information?
28. Would national privacy and confidentiality standards help ensure that data maintained in an immunization registry is protected?

Ensuring Provider Participation Questions To Be Considered
1. What type of resources (e.g., hardware, staff, etc.) are needed for you (provider/organization) to participate in a computerized registry?
2. What are the cost-related barriers that keep you (provider/organization) from participating in an immunization registry?
3. What cost should providers be responsible for, pertaining to participation in immunization registry systems?
4. What are the cost savings you would anticipate as a result of participating in a computerized registry (e.g., increased return visit form reminders, less personnel paperwork for preschool exams, etc.)?
5. How much time would you be willing to invest per patient visit (e.g., additional 1, 5, 7, 10 minutes) in the overall success of an immunization registry?
6. What type of user support would be needed in order for you (provider/organization) to participate in an immunization registry?
7. How would you (provider/organization) encourage providers and consumers in your community to participate in an immunization registry?
8. What community support would be necessary for you to participate in the immunization registry?
9. What benefits/value (e.g., immunization reminders, quick access to immunization histories, etc.) would a registry provide that would encourage your (provider/organization) participation?
10. What incentives should be offered to providers/organizations to participate in an immunization registry?
11. What barriers have you (provider/organization) encountered that have prevented you from participating in an immunization registry?
12. Is provider liability (e.g., disclosure of sensitive patient information) a barrier to participating in an immunization registry? Why?
13. How would an immunization registry impact your practice/organization?
14. Do you currently share immunization data with other providers electronically? For what purpose (e.g., billing, share group data, etc.)?
15. How (e.g., electronic record, paper record) is medical information maintained in your practice/organization?
16. Who should retain ownership of immunization records as they are distributed throughout an immunization registry?
17. How would you (provider/organization) use the data maintained in an immunization registry?
18. What type of quality control process would you (provider/organization) perform to ensure the accuracy and completeness of the immunization data entered into an immunization registry?
19. What type of security policies and procedures need to be in place for you to be confident that data are secure?
20. What functions should a registry perform in your office in order for you (provider/organization) to participate?
21. Do you have any advice or recommendations for NVAC/CDC/HHS related to the implementation of the network of state and community-based immunization registries? What should the role of the Federal Government be in this effort?
22. Have you received training on the use and maintenance of computerized medical information? Do you feel this training is needed to fully support the development and maintenance of immunization registries? Contact Person for More Information: Robbins Linkin, M.P.H., Ph.D., Chief, Systems Development Branch, Data Management Division, NIP, CDC, 1600 Clifton Road, NE, M/S E-62, Atlanta, GA 30333, telephone (404) 639-8728, e-mail nx3@cdc.gov.
23. How would you (provider/organization) use the data maintained in an immunization registry throughout an immunization registry?
24. Would you (provider/organization) perform in your office in order for you to be confident that data are secure?
25. Do you feel this training is needed to fully support the development and maintenance of immunization registries?
26. What functions should a registry perform in your office in order for you (provider/organization) to participate?
27. Do you have any advice or recommendations for NVAC/CDC/HHS related to the implementation of the network of state and community-based immunization registries? What should the role of the Federal Government be in this effort?
28. Have you received training on the use and maintenance of computerized medical information? Do you feel this training is needed to fully support the development and maintenance of immunization registries? Contact Person for More Information: Robbins Linkin, M.P.H., Ph.D., Chief, Systems Development Branch, Data Management Division, NIP, CDC, 1600 Clifton Road, NE, M/S E-62, Atlanta, GA 30333, telephone (404) 639-8728, e-mail nx3@cdc.gov.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.


This draft guidance is a revision of the guidance entitled “SUPAC-IR: Immediate Release Solid Oral Dosage Forms, Manufacturing Equipment Addendum” that published in October 1997, and the draft guidance is intended to supersede the previously published guidance. The draft guidance includes information on equipment used to manufacture modified release solid oral dosage form products as well as immediate release solid oral dosage form products and may be used to determine what documentation should be submitted to FDA regarding equipment changes made in accordance with the recommendations in sections V and VI of the SUPAC-IR guidance.
In order to receive copies of the draft guidance document entitled "Guidance Document for Industry and CDRH Staff for the Preparation of Investigational Device Exemptions and Premarket Approval Applications for Bone Growth Stimulator Devices" via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number (487) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance document may also do so using the World Wide Web (WWW). CDRH maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Web. Updated on a