Food and Drug Administration, HHS

§ 822.37 Plan uses investigators, stating the commitment to conduct the surveillance in accordance with the approved plan, any applicable FDA regulations, and any conditions of approval for your plan, such as reporting requirements;
(c) Your approved postmarket surveillance plan, with documentation of the date and reason for any deviation from the plan;
(d) All data collected and analyses conducted in support of your postmarket surveillance plan; and
(e) Any other records that we require to be maintained by regulation or by order, such as copies of signed consent documents, evidence of Institutional Review Board review and approval, etc.

§ 822.35 Can you inspect my manufacturing site or other sites involved in my postmarket surveillance plan?
We can review your postmarket surveillance programs during regularly scheduled inspections, inspections initiated to investigate recalls or other similar actions, and inspections initiated specifically to review your postmarket surveillance plan. We may also inspect any other person or site involved in your postmarket surveillance, such as investigators or contractors. Any person authorized to grant access to a facility must permit authorized FDA employees to enter and inspect any facility where the device is held or where records regarding postmarket surveillance are held.

§ 822.36 Can you inspect and copy the records related to my postmarket surveillance plan?
We may, at a reasonable time and in a reasonable manner, inspect and copy any records pertaining to the conduct of postmarket surveillance that are required to be kept by this regulation. You must be able to produce records and information required by this regulation that are in the possession of others under contract with you to conduct the postmarket surveillance. Those who have signed agreements or are under contract with you must also produce the records and information upon our request. This information must be produced within 72 hours of the initiation of the inspection. We generally will redact information pertaining to individual subjects prior to copying those records, unless there are extenuating circumstances.

§ 822.37 Under what circumstances would you inspect records identifying subjects?
We can inspect and copy records identifying subjects under the same circumstances that we can inspect any records relating to postmarket surveillance. We are likely to be interested in such records if we have reason to believe that required reports have not been submitted, or are incomplete, inaccurate, false, or misleading.