

**Analysis of Proposed Consent Order to Aid Public Comment**  
***In the Matter of EmpiriStat, Inc.***  
**File No. 182 3195**

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an agreement containing a consent order from EmpiriStat, Inc. (“EmpiriStat” or “Respondent”).

The proposed consent order (“proposed order”) has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received, and will decide whether it should withdraw from the agreement and take appropriate action or make final the agreement’s proposed order.

This matter concerns alleged false or misleading representations that EmpiriStat made concerning its participation in and compliance with the Privacy Shield framework agreed upon by the U.S. and the European Union (“EU”). The Privacy Shield framework allows U.S. companies to receive personal data transferred from the EU without violating EU. The frameworks consist of a set of principles and related requirements that have been deemed by the European Commission as providing “adequate” privacy protection. The principles include notice; choice; accountability for onward transfer; security; data integrity and purpose limitation; access; and recourse, enforcement, and liability. The related requirements include, for example, securing an independent recourse mechanism to handle any disputes about how the company handles information about EU citizens.

To participate in the frameworks, a company must comply with the Privacy Shield principles and self-certify that compliance to the U.S. Department of Commerce (“Commerce”). Commerce reviews companies’ self-certification applications and maintains a public website, <https://www.privacyshield.gov/list>, where it posts the names of companies who have completed the requirements for certification. Companies are required to recertify every year in order to continue benefitting from Privacy Shield.

EmpiriStat provides statistical analysis and clinical trial support services. According to the Commission’s complaint, EmpiriStat published on its website, <http://www.empiristat.com>, a privacy policy containing statements related to its participation in Privacy Shield.

The Commission’s proposed three-count complaint alleges that Respondent violated Section 5(a) of the Federal Trade Commission Act. Specifically, the proposed complaint alleges that Respondent engaged in a deceptive act or practice by falsely representing that it was a certified participant in the EU-U.S. and Swiss-U.S. Privacy Shield frameworks. The proposed complaint further alleges that Respondent engaged in deceptive acts or practices by representing that it complied with those frameworks when in fact it had failed to comply with certain Privacy Shield requirements.

Part I of the proposed order prohibits the company from making misrepresentations about its membership in any privacy or security program sponsored by the government or any other self-regulatory or standard-setting organization, including, but not limited to, the EU-U.S. Privacy Shield framework and the Swiss-U.S. Privacy Shield framework.

Part II of the proposed order requires that the company affirm to Commerce that it will either continue to apply the Privacy Shield framework principles to any data it received pursuant to frameworks or will delete or return such data.

Parts III through VI of the proposed order are reporting and compliance provisions. Part III requires acknowledgement of the order and dissemination of the order now and in the future to persons with responsibilities relating to the subject matter of the order. Part IV ensures notification to the FTC of changes in corporate status and mandates that the company submit an initial compliance report to the FTC. Part V requires the company to create certain documents relating to its compliance with the order for ten (10) years and to retain those documents for a five-year period. Part VI mandates that the company make available to the FTC information or subsequent compliance reports, as requested.

Part VII is a provision “sun-setting” the order after twenty (20) years, with certain exceptions.

The purpose of this analysis is to aid public comment on the proposed order. It is not intended to constitute an official interpretation of the complaint or proposed order, or to modify in any way the proposed order’s terms.